

US3162139 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:29:49

All time stamps listed in this document are displayed in GMT

US3162139

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 04:05:07

Generated On: 09 Jun 2021 15:29:49

[Participant ID](#)

US3162139

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

US3162139

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 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) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	69
Age Units	YEARS
Age (Derived)	69
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) 15 Feb 2021 04:19:37

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Date of Informed Consent (<i>dd MMM yyyy</i>)	18 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) 15 Feb 2021 04:19:37

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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) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	ATROPHIC VAGNITIS
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 (5)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	STRESS URINARY INCONTINENCE
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2008
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2008
Stop Year (derived)	2008

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	MULTIPLE VARICOSE VEINS, BILATERAL
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	MAMMARY HYPERPLASIA, BENIGN, BILATERAL
Start date (dd MMM yyyy)	UN UNK 1965
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	CARDIAC MURMUR
Start date (dd MMM yyyy)	UN UNK 1956
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 1956
Start Year (derived)	1956
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	ACID REFLUX
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 (11)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	ATYPICAL CHEST PAIN
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 29 Mar 2021 07:09:06

Generated On: 09 Jun 2021 15:29:49

Condition	INTERMITTENT APHTHOUS STOMATITIS
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 12:53
Height (xxx.x)	64 in
Weight (xxx.x)	156 lb
BMI (xxx.x)	26.83333 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) 15 Feb 2021 04:19:38

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 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) 15 Feb 2021 04:19:37

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Date of assessment (dd MMM yyyy) 18 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 2005

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 04:19:38

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

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) 15 Feb 2021 04:19:38

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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) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	18 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

What was the date of randomization? (dd MMM yyyy) 18 AUG 2020

What was the participant's randomization number? 186464

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) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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)	18 AUG 2020
Time of assessment (00:00-23:59)	12:53 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 12:53
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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)	18 AUG 2020
Time of assessment (00:00-23:59)	15:08 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 15:08
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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) 18 AUG 2020

What was the treatment time? (00:00-23:59) 14:31 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 14:31

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) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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

Collection date (dd MMM yyyy)	18 AUG 2020
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Collection time (00:00-23:59)	13:49 (24 HR)
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Collection date and time (derived)	18 AUG 2020 13:49
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US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:55	18 AUG 2020 13:55
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 AUG 2020 15:03

PC Open Date & Time

18 AUG 2020 14:51

PC Close Date & Time

18 AUG 2020 17:21

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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 97.3 °F

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

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

PC Time Stamp	18 AUG 2020 18:58
PC Open Date & Time	18 AUG 2020 18:16
PC Close Date & Time	19 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 12:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 06:27

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

97.6 °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

21 AUG 2020 22:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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

23 AUG 2020 02:22

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

23 AUG 2020 15:25

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 16:38

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

18 AUG 2020 15:06

PC Open Date & Time

18 AUG 2020 14:51

PC Close Date & Time

18 AUG 2020 17:21

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

18 AUG 2020 18:25

PC Open Date & Time

18 AUG 2020 18:16

PC Close Date & Time

19 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

19 AUG 2020 12:59

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

21 AUG 2020 06:21

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

21 AUG 2020 19:34

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

23 AUG 2020 02:23

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

23 AUG 2020 15:25

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

24 AUG 2020 16:38

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 15:07
PC Open Date & Time	18 AUG 2020 14:51
PC Close Date & Time	18 AUG 2020 17:21

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 18:24
PC Open Date & Time	18 AUG 2020 18:16
PC Close Date & Time	19 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 04:42
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

58 of 3397

EAB) (1725)

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 19:34
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 02:23
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 14:58
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 3397

EAB) (1725)

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 16:38
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 25 AUG 2020 16:41

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 9

Select one response below to indicate the level of your

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 ☐

PC Time stamp 26 AUG 2020 21:36

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 10

Select one response below to indicate the level of your

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 ☐

PC Time stamp

27 AUG 2020 13:19

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 11

Select one response below to indicate the level of your

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 ☐

PC Time stamp

28 AUG 2020 16:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 12

Select one response below to indicate the level of your

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 ☐

PC Time stamp

30 AUG 2020 07:07

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	25 AUG 2020 16:41
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	26 AUG 2020 21:36
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 10
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	27 AUG 2020 13:19
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 11

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

No ☒

Yes ☐

PC Time stamp

28 AUG 2020 16:00

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 12
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	30 AUG 2020 07:07
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3162139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:05:10

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:05:10

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	12:47 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 12:47
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	15 SEP 2020
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	15 SEP 2020 14:36
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	91 mmHg
Diastolic Blood Pressure units	MMHG

US3162139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 SEP 2020

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

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 13:57 (24 HR)

Treatment Date and Time (derived) 15 SEP 2020 13:57

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

US3162139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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

Collection date (dd MMM yyyy)	15 SEP 2020
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Collection time (00:00-23:59)	13:25 (24 HR)
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Collection date and time (derived)	15 SEP 2020 13:25
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US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Collection date (<i>dd MMM yyyy</i>)			15 SEP 2020
Lab Test	Was the sample collected?	Collection time (<i>00:00 - 23:59</i>)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:27	15 SEP 2020 13:27
Nasopharyngeal Swab 2	No		

US3162139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 14:31

PC Open Date & Time

15 SEP 2020 14:17

PC Close Date & Time

15 SEP 2020 16:47

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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 96.9 °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 19:38
PC Open Date & Time	15 SEP 2020 17:42
PC Close Date & Time	16 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 18:15

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

18 SEP 2020 08:04

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 19:51

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

19 SEP 2020 19:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

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 <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	98.1 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

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

PC Time Stamp	20 SEP 2020 16:25
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 17:23

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 14:30

PC Open Date & Time

15 SEP 2020 14:17

PC Close Date & Time

15 SEP 2020 16:47

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 19:38

PC Open Date & Time

15 SEP 2020 17:42

PC Close Date & Time

16 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 18:15

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 08:04

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

18 SEP 2020 19:50

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 19:42

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 SEP 2020 16:25

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:22

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 14:30
PC Open Date & Time	15 SEP 2020 14:17
PC Close Date & Time	15 SEP 2020 16:47

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

No ☒

Yes ☐

PC Time stamp	15 SEP 2020 19:39
PC Open Date & Time	15 SEP 2020 17:42
PC Close Date & Time	16 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

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 ☒

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 08:05
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

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 ☒

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 19:50
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 19:43
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

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 ☒

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EAB) (1725)

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US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 16:26
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 17:22
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3162139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	12 OCT 2020
--------------------------	-------------

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

Folder OID	VISIT3
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US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	9:23 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 9:23
Temperature (<i>xxx.x</i>)	37 C
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>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

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.

US3162139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 OCT 2020
Collection time (00:00-23:59)	9:38 (24 HR)
Collection date and time (derived)	12 OCT 2020 9:38

US3162139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:38

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	False
Body aches	True
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	18 OCT 2020 08:53:41
Patient Cloud Open Date & Time	18 OCT 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

22 OCT 2020 23:59

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

26 OCT 2020 07:40:28

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

01 NOV 2020 07:30:06

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 NOV 2020 07:43:50

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 NOV 2020 05:43:45
Patient Cloud Open Date & Time	19 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

26 NOV 2020 12:25:14

Patient Cloud Open Date & Time

26 NOV 2020 00:01

Patient Cloud Close Date & Time

30 NOV 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

04 DEC 2020 12:51:06

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

10 DEC 2020 08:43:54

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 10:14:33

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

26 DEC 2020 09:37:12

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

31 DEC 2020 09:54:54

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 JAN 2021 07:43:09

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

14 JAN 2021 07:40:08

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

21 JAN 2021 07:52:15

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

28 JAN 2021 10:49:15

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

05 FEB 2021 09:53:41

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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	11 FEB 2021 07:20:38
Patient Cloud Open Date & Time	11 FEB 2021 00:01
Patient Cloud Close Date & Time	15 FEB 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 13:15:13

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 15:40:54

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

06 MAR 2021 10:53:55

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

12 MAR 2021 09:43:14

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

18 MAR 2021 08:18:00

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

25 MAR 2021 08:00:06

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 APR 2021 09:16:46
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 07:29:50

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

16 APR 2021 07:15:32

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

23 APR 2021 19:53:08

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

30 APR 2021 11:47:43

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	28 JUN 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	26 JUL 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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°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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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°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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 446

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

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

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

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

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

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

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

25 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 JAN 2022 00:01
Patient Cloud Close Date & Time	10 JAN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

27 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JAN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 APR 2022 00:01
Patient Cloud Close Date & Time	18 APR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 JUL 2022 00:01
Patient Cloud Close Date & Time	11 JUL 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

11 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

15 AUG 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 OCT 2022 00:01
Patient Cloud Close Date & Time	17 OCT 2022 23:59

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

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

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3162139

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:29:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
Yes	No	06 MAR 2021 10:54:35

US3162139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 13 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	23 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
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US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3162139

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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.

US3162139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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

Collection date (dd MMM yyyy)	23 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	12:30 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	23 MAR 2021 12:30
------------------------------------	-------------------

US3162139

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 APR 2021

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Date of Contact	18 OCT 2020
Time of Contact	17:41
Date and Time of Contact (derived)	18 OCT 2020 17:41
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Date	19 OCT 2020
------	-------------

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

O2 Saturation	96 %
---------------	------

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

Temperature	102.4 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Date	20 OCT 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	98.1 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Date	17 OCT 2020
------	-------------

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

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

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

Temperature	102.4 F
-------------	---------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 OCT 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	101.0 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Date	21 OCT 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Date of Contact	25 AUG 2020
Time of Contact	08:27
Date and Time of Contact (derived)	25 AUG 2020 08:27
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	26 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	99.1 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

Date	27 AUG 2020
------	-------------

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

O2 Saturation	95 %
---------------	------

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

Temperature	97.6 F
-------------	--------

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

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

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

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

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Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

Date	28 AUG 2020
------	-------------

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

O2 Saturation	99 %
---------------	------

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

Temperature	97.8 F
-------------	--------

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

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

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

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

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Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 AUG 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	30 AUG 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

Date	31 AUG 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	97.7 F
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Date of Visit	26 AUG 2020
Was the Subject Tested For SARS-CoV-2 by RT-PCR?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Did Subject Test Positive For SARS-CoV-2 by RT-PCR?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Date of Test	26 AUG 2020
Type of Test Performed	Nasopharyngeal Swab <input checked="" type="radio"/> Nasal Swab <input type="radio"/> Saliva Test <input type="radio"/> Other <input type="radio"/>
Other, specify	
Was this diagnostic test performed at a lab other than the Study Central Lab?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If yes, provide lab information below	
Lab/ Institution Test Performed	
CLIA Certified?	Yes <input type="radio"/> No <input type="radio"/>
COVID-19 Positive (CSA Programming Field Only)	0

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

[Generate Next COVID-19 Assessment](#)

Yes ☒
No ☐

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	28 AUG 2020
Day 5	Yes	30 AUG 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 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	SICKD1

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 AUG 2020
Time of assessment (00:00-23:59)	16:55 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 16:55
Height (xxx.x)	162.6 cm
Weight (xxx.x)	71.7 kg
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	149 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162139

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3162139

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

26 AUG 2020

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	19 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SICKD1
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US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 11:48
Height (xxx.x)	162.6 cm
Weight (xxx.x)	71 kg
Temperature (xxx.x)	38.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3162139

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3162139

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3162139

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

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	25 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3162139

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Date of updated informed consent (dd MMM yyyy)	25 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 (dd MMM yyyy)	25 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

US3162139

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Height	64 in
Weight	156 lb
BMI (xxx.x)	26.83333

US3162139

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Height	64 in
Weight	156 lb
BMI (xxx.x)	26.83333
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 JAN 2021
Time of assessment (00:00-23:59)	10:48 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 10:48
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG

US3162139

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Height	64 in
Weight	156 lb
BMI (xxx.x)	26.83333
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)	25 JAN 2021
Time of assessment (00:00-23:59)	13:29 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 13:29
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify _____	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	96 mmHg
Diastolic Blood Pressure units	MMHG

US3162139

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

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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.

US3162139

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

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 12:54 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 12:54

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

US3162139

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00-23:59)	11:08 (24 HR)
Collection date and time (derived)	25 JAN 2021 11:08

US3162139

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	11:02
Collection Date and Time (derived)	25 JAN 2021 11:02

US3162139

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

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:05:09

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 04:19:37

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	22 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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)	22 FEB 2021
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 11:38
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)	52 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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)	22 FEB 2021
Time of assessment (00:00-23:59)	13:00 (24 HR)
Vital Signs Date and Time (derived)	22 FEB 2021 13:00
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)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3162139

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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.

US3162139

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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) 22 FEB 2021

What was the treatment time? (00:00-23:59) 12:25 (24 HR)

Treatment Date and Time (derived) 22 FEB 2021 12:25

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

US3162139

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3162139

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3162139

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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

Visit date (dd MMM yyyy)	23 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD57
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US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

Time of assessment (00:00-23:59) _____

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3162139

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

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.

US3162139

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	23 MAR 2021
Collection time (<i>00:00-23:59</i>)	12:30 (24 HR)
Collection date and time (derived)	23 MAR 2021 12:30

US3162139

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 04:05:07

Generated On: 09 Jun 2021 15:29:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3162139

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input 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)	23 AUG 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)	29 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

AEID

Adverse event

FEBRILE REACTION TO
SHINGRIX VACCINE

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

17 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

22 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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EAB) (1725)

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

AEID	USA-US074-2021-MRNA-1273-P30 1000013
Adverse event	WORSENING OF HYPERTENSION
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)	16 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	16 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	17 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

SUBJECT HAS HYPERTENSION,
AND ON 16FEB2021, HER
SYSTOLIC BP WAS 185 ON
HOME UNIT. KAISER NURSE
ADVISED HER TO GO TO ER
AND THERE, IT WAS 183. SHE
WAS ADMITTED OVERNIGHT
SO SHE COULD HAVE WORKUP
THE NEXT MORNING,
INCLUDING STRESS TEST.
AFTER THE WORKUP, SHE WAS
DISCHARGED.
HYDROCHLOROTHIAZIDE WAS
STOPPED AND LISINOPRIL AND
METOPROLOL WERE STARTED
AND BY 17FEB21, HER BP WAS
CONTROLLED.

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

AEID	USA-US074-2021-MRNA-1273-P30 1000013
Adverse event	WORSENING OF ATYPICAL CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	1 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" 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)	16 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	17 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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SUBJECT WENT TO ER ON 16FEB21 BECAUSE HER BP WAS ELEVATED, BUT ER PHYSICIAN ELICITED A HISTORY OF ATYPICAL CHEST PAIN THAT HAD BEEN OCCURRING SINCE 2001, BUT HAD WORSENER AROUND 01FEB21. ON THE BASIS OF THIS, THE SUBJECT WAS ADMITTED TO RULE OUT MYOCARDIAL DISEASE. THIS WAS THE ACTUAL SAE, NOT THE ELEVATED BP, BUT IT WAS CLARIFIED ONLY AFTER SUBJECT HOSPITAL RECORDS WERE RECEIVED. SUBJECT'S TROPONIN WAS SLIGHTLY ELEVATED (.06, WITH NORMAL BEING <.03 NG/ML). THIS DECREASED TO .05. HER ECG WAS NORMAL. MYOCARDIAL PERFUSION SCAN WAS NORMAL. STRESS TEST WITH NUCLEAR IMAGING WAS NORMAL. TRANSTHORACIC ECHO SHOWED NORMAL EJECTION FRACTION AND WALL MOTION. SUBJECT HAD HYPOKALEMIA ON 16FEB21,(POTASSIUM 3.3 MEQ/LITER, WITH NORMAL RANGE BEING 3.5-5 MEQ/LITER) WHICH CORRECTED TO 3.6 AFTER A KCL BOLUS. HER ATORVASTATIN WAS INCREASED TO 40 MG AND ASPIRIN 81 MG DAILY WAS STARTED. SHE WAS DISCHARGED HOME ON 17FEB21

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

AEID	
Adverse event	HYPOKALEMIA
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)	16 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC RIGHT KNEE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

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

THREE TIMES PER WEEK

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) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ESTRADIOL VAGINAL RING

Prophylaxis Yes ☐
No ☒

Indication ATROPHIC VAGINITIS

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS

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) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input checked="" type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication FAMOTIDINE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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Name of Medication VITAMIN B12

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 2500

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

If dose unit is Other, specify MCG

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

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	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"/>

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication CALCIUM/VIT D

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 1200/1000

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

If dose unit is Other, specify MG/IU

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 (8)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication HYALURONIC ACID

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

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 (10)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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 (11)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication SHINGRIX

Prophylaxis Yes ☒
No ☐

Indication SHINGLES PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication REACTION TO SHINGRIX
VACCINE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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	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)	17 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication REACTION TO SHINGRIX
VACCINE

Dose per administration 500

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 (13)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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	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)	18 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PREVENTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF
HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPOKALEMIA

Dose per administration 40

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

If dose unit is Other, specify MEQ

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)

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	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication PREVENT THROMBOTIC EVENT

Dose per administration 5000

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 (18)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 17 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROTECTION

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 (20)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication REGADENOSON (CONTRAST
AGENT FOR MYOCARDIAL
PERFUSION SCAN)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ATYPICAL
CHEST PAIN

Dose per administration 0.4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Transdermal	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication THALLIUM (AGENT FOR
STRESS TEST WITH NUCLEAR
IMAGING)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ATYPICAL
CHEST PAIN

Dose per administration 3.6

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

If dose unit is Other, specify MILLICURIE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Transdermal	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication TC SESTAMIBI (AGENT FOR
STRESS TEST WITH NUCLEAR
IMAGING)

Prophylaxis Yes ☐
No ☒

Indication WORSENING OF ATYPICAL
CHEST PAIN

Dose per administration 26.9

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

If dose unit is Other, specify MILLICURIE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Transdermal	<input type="checkbox"/>
	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 17 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication METOPROLOL TARTRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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)	20 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)	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 (26)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ESTRADIOL .01% VAGINAL CREAM

Prophylaxis Yes ☐
No ☒

Indication ATROPHIC VAGINITIS

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 (26)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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 checked="" 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)		8 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input checked="" type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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Name of Medication KENALOG IN ORABASE (0.1%
TRIAMCINOLONE PASTE)

Prophylaxis Yes ☐
No ☒

Indication INTERMITTENT APHTHOUS
STOMATITIS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 (27)

Data signed: (b) (4) 24 Apr 2021 23:07:14

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	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 2001	
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 (28)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication UNKNOWN

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication CARDIAC PROPHYLAXIS

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		16 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 16 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication RESTYLANE

Prophylaxis Yes ☐
No ☒

Indication COSMETIC- UPPER LIP

Dose per administration UNKNOWN

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

If dose unit is Other, specify VIAL

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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 1996	
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"/>

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

Name of Medication SHINGRIX

Prophylaxis Yes ☒
No ☐

Indication PREVENT SHINGLES

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 24 Apr 2021 23:07:14

Generated On: 09 Jun 2021 15:29:49

	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)		05 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 04:05:08

Generated On: 09 Jun 2021 15:29:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 08 Apr 2021 21:29:48

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 JAN 2021	RIGHT KNEE XRAY	Medical History	
21 JAN 2021	RIGHT BREAST BIOPSY	Diagnostic	
17 FEB 2021	MYOCARDIAL PERFUSION SCAN	Diagnostic	
17 FEB 2021	TRANSTHORACIC ECHOCARDIOGRAM	Diagnostic	
17 FEB 2021	CARDIAC STRESS TEST WITH NUCLEAR IMAGING	Diagnostic	
16 FEB 2021	ELECTROCARDIOGRAM	Diagnostic	
16 FEB 2021	CHEST XRAY	Diagnostic	

US3162139

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:29:49

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3162139

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:29:49

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 ☐

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

SAEID	USA-US074-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

SAEID	USA-US074-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/FEB/2021 10:57
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

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

SAEID	USA-US074-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	08/MAR/2021 11:37
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

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

SAEID	USA-US074-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	24/MAR/2021 11:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

SAEID	USA-US074-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/APR/2021 06:11
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Data signed: (b) (4) 24 Apr 2021 23:07:15

Generated On: 09 Jun 2021 15:29:49

SAEID	USA-US074-2021-MRNA-1273-P301000013
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	JUDITH
Investigator's Last Name	KIRSTEIN
Site Address: Street	264 N HIGHLAND SPRINGS AVE, SUITE 4
Site Address: City	BANNING
Site Address: State	CA
Site Address: Postal Code	92220
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	19/APR/2021 11:54
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

US3162139 (Prod: Advanced Clinical Research - Rancho Paseo - ERN - PPDS)

US3162139

Form: Participant Creation

Generated On: 09 Jun 2021 15:29:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'US3162139'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:39:16

US3162139

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:40:09

US3162139

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:39:17

US3162139

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	18 Aug 2020 21:40:09

US3162139

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'SCRN'	System	18 Aug 2020 21:40:09

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered (b) (6) 1951'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:39:18

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '69'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'YEARS'	System	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '69'	System	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Female (F)'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'I'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:29:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:41:37

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Aug 2020'	System	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2020'	System	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:41:56

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 19:39:17

US3162139

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:29:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'I'	System	18 Aug 2020 21:42:13

US3162139

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:42:13

US3162139

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:29:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:42:29

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:48:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:48:26
Data point term sent to Coder	System	19 Aug 2020 04:47:29
User entered 'anxiety'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2015'	System	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2015'	System	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:46:52

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:48:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:48:26
Data point term sent to Coder	System	19 Aug 2020 04:47:29
User entered 'hypertension'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2003'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2003'	System	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2003'	System	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:47:02

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:48:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:48:26
Data point term sent to Coder	System	19 Aug 2020 04:47:29
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2004'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2004'	System	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2004'	System	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:47:14

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menopause related conditions, HLT: Menopausal effects on the genitourinary tract, PT: Atrophic vulvovaginitis, LLT: Atrophic vaginitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:28:22
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:28:22
Data point term sent to Coder	System	19 Aug 2020 04:48:30
User entered 'atrophic vagnitis'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2010'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2010'	System	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2010'	System	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:47:33

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:58:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:58:50
Data point term sent to Coder	System	15 Sep 2020 19:58:24
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:57:30
User entered 'POSTMENOPAUSAL' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:57:30
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Menopause, LLT: Menopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:49:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:49:11
Data point term sent to Coder	System	19 Aug 2020 04:48:32
User entered 'menopause'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2005'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:57:30
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User closed query 'Per DM CLR: Please review the stop date of MENOPAUSE, as this condition is not expected to resolve. Please review and update eCRF if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:41:07
Query 'Per DM CLR: Please review the stop date of MENOPAUSE, as this condition is not expected to resolve. Please review and update eCRF if appropriate or provide explanation. ' answered with 'UPDATED PER QUERY' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:57:42
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:57:30
User opened query 'Per DM CLR: Please review the stop date of MENOPAUSE, as this condition is not expected to resolve. Please review and update eCRF if appropriate or provide explanation. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:25:13
User entered 'un UNK 2005'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2005'	System	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2005'	System	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	15 Sep 2020 19:57:30
User entered 'Jan 2005'	System	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	15 Sep 2020 19:57:30
User entered '2005'	System	19 Aug 2020 04:47:50

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Stress urinary incontinence, LLT: Stress urinary incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:49:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:49:11
Data point term sent to Coder	System	19 Aug 2020 04:48:32
User entered 'stress urinary incontinence'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2005'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2008'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2005'	System	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2005'	System	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2008'	System	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2008'	System	19 Aug 2020 04:48:24

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User closed query 'Per DM CLR: Please specify the location of MULTIPLE VARICOSE VEINS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:47:00
User coded data point as SOC: Vascular disorders, HLGT: Venous varices, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:32:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Sep 2020 14:32:43
Data point term sent to Coder	System	15 Sep 2020 20:06:49
Query 'Per DM CLR: Please specify the location of MULTIPLE VARICOSE VEINS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 20:06:42
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 20:06:19
User entered 'MULTIPLE VARICOSE VEINS, BILATERAL' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 20:06:19
User opened query 'Per DM CLR: Please specify the location of MULTIPLE VARICOSE VEINS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:26:45
User coded data point as SOC: Vascular disorders, HLGT: Venous varices, HLT: Varicose veins NEC, PT: Varicose vein, LLT: Varicose veins - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:17:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:17:15

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Aug 2020 04:49:32
User entered 'multiple varicose veins'	Jared Bradshaw (b) (4)	19 Aug 2020 04:48:48
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 1980'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 1980'	System	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '1980'	System	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:48:48

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User closed query 'Per DM CLR: Please update the condition to confirm if the MAMMARY HYPERPLASIA was benign or cancerous, as well as it's laterality. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:49:43
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Breast hyperplasia, LLT: Bilateral mammary hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 20:07:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 20:07:03
Data point term sent to Coder	System	15 Sep 2020 19:52:06
Query 'Per DM CLR: Please update the condition to confirm if the MAMMARY HYPERPLASIA was benign or cancerous, as well as it's laterality. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' answered with 'UPDATED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:52:03
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:51:54
User entered 'MAMMARY HYPERPLASIA, BENIGN, BILATERAL' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:51:54
User opened query 'Per DM CLR: Please update the condition to confirm if the MAMMARY HYPERPLASIA was benign or cancerous, as well as it's laterality. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 11:27:26

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Breast disorders, HLT: Benign and malignant breast neoplasms, PT: Breast hyperplasia, LLT: Breast hyperplasia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:14:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 07:14:20
Data point term sent to Coder	System	19 Aug 2020 04:49:33
User entered 'mammary hyperplasia'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 1965'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2003'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 1965'	System	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '1965'	System	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2003'	System	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2003'	System	19 Aug 2020 04:49:29

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Investigations, HLG: Cardiac and vascular investigations (excl enzyme tests), HLT: Cardiac auscultatory investigations, PT: Cardiac murmur, LLT: Cardiac murmur - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:51:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:51:11
Data point term sent to Coder	System	19 Aug 2020 04:50:33
User entered 'cardiac murmur'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 1956'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 1956'	System	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '1956'	System	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:49:50

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:51:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:51:11
Data point term sent to Coder	System	19 Aug 2020 04:50:35
User entered 'acid reflux'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'un UNK 2010'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2010'	System	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2010'	System	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	19 Aug 2020 04:50:01

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 07:09:06
	(b) (4)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 17:00:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Mar 2021 17:00:38
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 16:59:41
User entered 'atypical chest pain'	Judith Kirstein (b) (4)	23 Mar 2021 16:58:47
	(b) (4)	

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered 'UN UNK 2001'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 07:09:06
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 16:58:47
	(b) (4)	

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2001'	System	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2001'	System	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	23 Mar 2021 16:58:47

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Stomatitis and ulceration, PT: Aphthous ulcer, LLT: Aphthous stomatitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:37:28
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 06:37:28
Data point term sent to Coder	System	23 Mar 2021 17:25:20
User entered 'Intermittent aphthous stomatitis'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered 'UN UNK 2001'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 07:09:06
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:24:59
	(b) (4)	

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 07:09:06
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'Jan 2001'	System	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '2001'	System	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered empty.	System	23 Mar 2021 17:24:59

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '12:53'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered '18 Aug 2020 12:53'	System	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '64' in	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50
DataPoint set to visible.	System	18 Aug 2020 21:42:13

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '156' lb	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50
DataPoint set to visible.	System	18 Aug 2020 21:42:13

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
Amendment Manager: User entered '26.83333'	System	17 Sep 2020 00:12:53
User entered '26.8'	System	19 Aug 2020 04:50:50
DataPoint set to visible.	System	18 Aug 2020 21:42:13

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'kg/m2'	System	19 Aug 2020 04:50:50
DataPoint set to visible.	System	18 Aug 2020 21:42:13

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 17:18:03
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'UPDATED' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:30
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 17:34:42
User entered '97.6' F	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:30
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:30
User entered '73'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'bpm'	System	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:30
User entered '15'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'breaths/min'	System	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:30
User entered '123'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'mmHg'	System	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 19:53:30
User entered '75'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User entered 'mmHg'	System	19 Aug 2020 04:50:50

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38

US3162139

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38

US3162139

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:44:53

US3162139

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 20:59:51
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	16 Sep 2020 18:59:30
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	07 Sep 2020 13:43:31
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 19:09:43
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:44:53

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'UN UNK 2005'	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 15:29:49

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:44:33

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'I'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '0'	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:29:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 07:25:38
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:43:28

US3162139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:58

US3162139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:50:58

US3162139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:50:58
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'VISIT1'	System	19 Aug 2020 04:50:58

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 21:04:22

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:24:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:24:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 21:04:22
User entered '186464' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 21:04:22

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	18 Aug 2020 21:04:22

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:51:19

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:51:19

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:51:19

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:51:19

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:51:19

US3162139

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:29:49

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:35:12
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:23:24

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User accepted default value 'Pre-Dose (PREDOSE)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '12:53'	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '18 Aug 2020 12:53'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '97.6' F	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '73'	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'bpm'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '15'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'breaths/min'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '123'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '75'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered missing code ND - Not Done.	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User accepted default value 'Post-Dose (POSTDOSE)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:24:44
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		19 Aug 2020 04:52:51
User entered '15:08'	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '18 Aug 2020 15:08'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '97.6' F	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Oral (Oral)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '74'	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:51
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'bpm'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '14'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'breaths/min'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '140'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '83'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	19 Aug 2020 04:52:51

US3162139

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'No (N)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:52:59
	(b) (4)	

US3162139

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:52:59

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '14:31'	(b) (4), (b) (6)	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '18 Aug 2020 14:31'	System	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'ONCE'	System	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 21:45:40

US3162139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:49:33

US3162139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:49:33

US3162139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User closed query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 21:55:29
User entered '13:49' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:55:29
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 21:49:33
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:49:33

US3162139

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '18 Aug 2020 13:49'	System	18 Aug 2020 21:55:29
User entered empty.	System	18 Aug 2020 21:49:33

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '18 Aug 2020'	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '13:55'	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered '18 Aug 2020 13:55'	System	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered empty.	System	18 Aug 2020 21:59:10

US3162139

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Aug 2020 22:00:36

US3162139

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'I'	System	18 Aug 2020 22:00:36

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:02:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58036874-03dc-4145-81a6-34397d34d636'	System	18 Aug 2020 22:03:09
User entered 'Yes (Y)'	System	18 Aug 2020 22:03:09

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:02:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58036874-03dc-4145-81a6-34397d34d636'	System	18 Aug 2020 22:03:09
User entered '97.6'	System	18 Aug 2020 22:03:09

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:02:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58036874-03dc-4145-81a6-34397d34d636'	System	18 Aug 2020 22:03:09
User entered 'No (N)'	System	18 Aug 2020 22:03:09

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:03:04', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58036874-03dc-4145-81a6-34397d34d636'	System	18 Aug 2020 22:03:09
User entered '18 Aug 2020 15:03'	System	18 Aug 2020 22:03:09

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 14:51'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 17:21'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:57:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a1bf4510-2890-4856-9708-d4c578132739'	System	19 Aug 2020 01:58:29
User entered 'Yes (Y)'	System	19 Aug 2020 01:58:29

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:58:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a1bf4510-2890-4856-9708-d4c578132739' User entered '97.3'	System	19 Aug 2020 01:58:29
	System	19 Aug 2020 01:58:29

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:58:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a1bf4510-2890-4856-9708-d4c578132739'	System	19 Aug 2020 01:58:29
User entered 'No (N)'	System	19 Aug 2020 01:58:29

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:58:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a1bf4510-2890-4856-9708-d4c578132739'	System	19 Aug 2020 01:58:29
User entered '18 Aug 2020 18:58'	System	19 Aug 2020 01:58:29

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 18:16'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 2'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:18', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f48de7e-a021-4ebc-a3d8-c8543008a4d5' User entered 'Yes (Y)'	System	19 Aug 2020 19:59:36
	System	19 Aug 2020 19:59:36

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:23', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f48de7e-a021-4ebc-a3d8-c8543008a4d5' User entered '98.3'	System	19 Aug 2020 19:59:36
	System	19 Aug 2020 19:59:36

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f48de7e-a021-4ebc-a3d8-c8543008a4d5'	System	19 Aug 2020 19:59:36
User entered 'No (N)'	System	19 Aug 2020 19:59:36

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f48de7e-a021-4ebc-a3d8-c8543008a4d5'	System	19 Aug 2020 19:59:36
User entered '19 Aug 2020 12:59'	System	19 Aug 2020 19:59:36

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 3'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:27:25', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a5295b19-21fe-4690-ab6e-41af8e993dec' User entered 'Yes (Y)'	System	21 Aug 2020 13:28:18
	System	21 Aug 2020 13:28:18

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:27:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a5295b19-21fe-4690-ab6e-41af8e993dec' User entered '97.5'	System	21 Aug 2020 13:28:18
	System	21 Aug 2020 13:28:18

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:27:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a5295b19-21fe-4690-ab6e-41af8e993dec'	System	21 Aug 2020 13:28:18
User entered 'No (N)'	System	21 Aug 2020 13:28:18

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:27:58', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a5295b19-21fe-4690-ab6e-41af8e993dec'	System	21 Aug 2020 13:28:18
User entered '21 Aug 2020 06:27'	System	21 Aug 2020 13:28:18

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 4'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T22:04:19', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6cc19bc-0d38-4036-87d8-bd129e64c41d' User entered 'Yes (Y)'	System	22 Aug 2020 05:04:39
	System	22 Aug 2020 05:04:39

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T22:04:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6cc19bc-0d38-4036-87d8-bd129e64c41d' User entered '97.6'	System	22 Aug 2020 05:04:39
	System	22 Aug 2020 05:04:39

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T22:04:13', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6cc19bc-0d38-4036-87d8-bd129e64c41d' User entered 'No (N)'	System	22 Aug 2020 05:04:39
	System	22 Aug 2020 05:04:39

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T22:04:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6cc19bc-0d38-4036-87d8-bd129e64c41d' User entered '21 Aug 2020 22:04'	System	22 Aug 2020 05:04:39
	System	22 Aug 2020 05:04:39

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 5'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:17', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f02a507b-d56e-47f3-afbe-97d62a65a402'	System	23 Aug 2020 09:22:40
User entered 'Yes (Y)'	System	23 Aug 2020 09:22:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:25', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f02a507b-d56e-47f3-afbe-97d62a65a402'	System	23 Aug 2020 09:22:40
User entered '96.8'	System	23 Aug 2020 09:22:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f02a507b-d56e-47f3-afbe-97d62a65a402'	System	23 Aug 2020 09:22:40
User entered 'No (N)'	System	23 Aug 2020 09:22:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f02a507b-d56e-47f3-afbe-97d62a65a402'	System	23 Aug 2020 09:22:40
User entered '23 Aug 2020 02:22'	System	23 Aug 2020 09:22:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 6'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:25:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3990ca37-b1e7-43d7-bbce-d62e9b7f27ef' User entered 'Yes (Y)'	System	23 Aug 2020 22:25:42
	System	23 Aug 2020 22:25:42

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:25:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3990ca37-b1e7-43d7-bbce-d62e9b7f27ef' User entered '97.7'	System	23 Aug 2020 22:25:42
	System	23 Aug 2020 22:25:42

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:25:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3990ca37-b1e7-43d7-bbce-d62e9b7f27ef'	System	23 Aug 2020 22:25:42
User entered 'No (N)'	System	23 Aug 2020 22:25:42

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:25:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3990ca37-b1e7-43d7-bbce-d62e9b7f27ef' User entered '23 Aug 2020 15:25'	System	23 Aug 2020 22:25:42
	System	23 Aug 2020 22:25:42

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 7'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:37:54', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '12f3cdb1-39ba-4230-88a7-1b8ab442955d' User entered 'Yes (Y)'	System	24 Aug 2020 23:38:14
	System	24 Aug 2020 23:38:14

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '12f3cdb1-39ba-4230-88a7-1b8ab442955d' User entered '97.7'	System	24 Aug 2020 23:38:14
	System	24 Aug 2020 23:38:14

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '12f3cdb1-39ba-4230-88a7-1b8ab442955d' User entered 'No (N)'	System	24 Aug 2020 23:38:14
	System	24 Aug 2020 23:38:14

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '12f3cdb1-39ba-4230-88a7-1b8ab442955d' User entered '24 Aug 2020 16:38'	System	24 Aug 2020 23:38:14
	System	24 Aug 2020 23:38:14

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:03:50', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ea029cc7-49d7-4b57-ab86-6c768fe89e71' User entered 'None (1)'	System	18 Aug 2020 22:06:20
	System	18 Aug 2020 22:06:20

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:05:50', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ea029cc7-49d7-4b57-ab86-6c768fe89e71' User entered 'No (N)'	System	18 Aug 2020 22:06:20
	System	18 Aug 2020 22:06:20

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:05:57', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ea029cc7-49d7-4b57-ab86-6c768fe89e71' User entered 'No (N)'	System	18 Aug 2020 22:06:20
	System	18 Aug 2020 22:06:20

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:06:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ea029cc7-49d7-4b57-ab86-6c768fe89e71'	System	18 Aug 2020 22:06:20
User entered 'None (1)'	System	18 Aug 2020 22:06:20

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:06:18', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ea029cc7-49d7-4b57-ab86-6c768fe89e71' User entered '18 Aug 2020 15:06'	System	18 Aug 2020 22:06:20
	System	18 Aug 2020 22:06:20

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 14:51'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 17:21'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:24:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e53a23d7-036d-428a-b8e6-4c079d8fe27a'	System	19 Aug 2020 01:25:13
User entered 'None (1)'	System	19 Aug 2020 01:25:13

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:24:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e53a23d7-036d-428a-b8e6-4c079d8fe27a' User entered 'No (N)'	System	19 Aug 2020 01:25:13
	System	19 Aug 2020 01:25:13

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:24:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e53a23d7-036d-428a-b8e6-4c079d8fe27a' User entered 'No (N)'	System	19 Aug 2020 01:25:13
	System	19 Aug 2020 01:25:13

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:24:59', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e53a23d7-036d-428a-b8e6-4c079d8fe27a'	System	19 Aug 2020 01:25:13
User entered 'None (1)'	System	19 Aug 2020 01:25:13

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:25:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e53a23d7-036d-428a-b8e6-4c079d8fe27a'	System	19 Aug 2020 01:25:13
User entered '18 Aug 2020 18:25'	System	19 Aug 2020 01:25:13

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 18:16'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 2'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:39', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ab51d194-5973-4920-abd9-e5f14d926000'	System	19 Aug 2020 19:59:57
User entered 'None (1)'	System	19 Aug 2020 19:59:57

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ab51d194-5973-4920-abd9-e5f14d926000'	System	19 Aug 2020 19:59:57
User entered 'No (N)'	System	19 Aug 2020 19:59:57

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:48', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ab51d194-5973-4920-abd9-e5f14d926000'	System	19 Aug 2020 19:59:57
User entered 'No (N)'	System	19 Aug 2020 19:59:57

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ab51d194-5973-4920-abd9-e5f14d926000'	System	19 Aug 2020 19:59:57
User entered 'None (1)'	System	19 Aug 2020 19:59:57

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-19T12:59:55', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ab51d194-5973-4920-abd9-e5f14d926000' User entered '19 Aug 2020 12:59'	System	19 Aug 2020 19:59:57
	System	19 Aug 2020 19:59:57

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 3'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:23', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd4dd4a10-2d7b-470b-96cb-2985b6512c97'	System	21 Aug 2020 13:22:01
User entered 'None (1)'	System	21 Aug 2020 13:22:01

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd4dd4a10-2d7b-470b-96cb-2985b6512c97'	System	21 Aug 2020 13:22:01
User entered 'No (N)'	System	21 Aug 2020 13:22:01

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd4dd4a10-2d7b-470b-96cb-2985b6512c97'	System	21 Aug 2020 13:22:01
User entered 'No (N)'	System	21 Aug 2020 13:22:01

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:54', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd4dd4a10-2d7b-470b-96cb-2985b6512c97'	System	21 Aug 2020 13:22:01
User entered 'None (1)'	System	21 Aug 2020 13:22:01

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:59', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd4dd4a10-2d7b-470b-96cb-2985b6512c97'	System	21 Aug 2020 13:22:01
User entered '21 Aug 2020 06:21'	System	21 Aug 2020 13:22:01

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 4'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:02', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '73345952-16aa-469a-94d6-40f061f609c8'	System	22 Aug 2020 02:34:24
User entered 'None (1)'	System	22 Aug 2020 02:34:24

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '73345952-16aa-469a-94d6-40f061f609c8'	System	22 Aug 2020 02:34:24
User entered 'No (N)'	System	22 Aug 2020 02:34:24

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:11', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '73345952-16aa-469a-94d6-40f061f609c8'	System	22 Aug 2020 02:34:24
User entered 'No (N)'	System	22 Aug 2020 02:34:24

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '73345952-16aa-469a-94d6-40f061f609c8'	System	22 Aug 2020 02:34:24
User entered 'None (1)'	System	22 Aug 2020 02:34:24

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:21', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '73345952-16aa-469a-94d6-40f061f609c8'	System	22 Aug 2020 02:34:24
User entered '21 Aug 2020 19:34'	System	22 Aug 2020 02:34:24

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 5'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '19a93a64-3cdd-4178-833a-99e537cd86ff'	System	23 Aug 2020 09:23:03
User entered 'None (1)'	System	23 Aug 2020 09:23:03

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '19a93a64-3cdd-4178-833a-99e537cd86ff' User entered 'No (N)'	System	23 Aug 2020 09:23:03
	System	23 Aug 2020 09:23:03

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:52', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '19a93a64-3cdd-4178-833a-99e537cd86ff' User entered 'No (N)'	System	23 Aug 2020 09:23:03
	System	23 Aug 2020 09:23:03

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:22:55', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '19a93a64-3cdd-4178-833a-99e537cd86ff' User entered 'None (1)'	System	23 Aug 2020 09:23:03
	System	23 Aug 2020 09:23:03

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:02', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '19a93a64-3cdd-4178-833a-99e537cd86ff' User entered '23 Aug 2020 02:23'	System	23 Aug 2020 09:23:03
	System	23 Aug 2020 09:23:03

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 6'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:24:40', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3dc8f98d-d8ad-4eb9-a986-c4996db8829f' User entered 'None (1)'	System	23 Aug 2020 22:25:15
	System	23 Aug 2020 22:25:15

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:24:43', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3dc8f98d-d8ad-4eb9-a986-c4996db8829f' User entered 'No (N)'	System	23 Aug 2020 22:25:15
	System	23 Aug 2020 22:25:15

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:24:46', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3dc8f98d-d8ad-4eb9-a986-c4996db8829f' User entered 'No (N)'	System	23 Aug 2020 22:25:15
	System	23 Aug 2020 22:25:15

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:24:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3dc8f98d-d8ad-4eb9-a986-c4996db8829f' User entered 'None (1)'	System	23 Aug 2020 22:25:15
	System	23 Aug 2020 22:25:15

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T15:25:14', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3dc8f98d-d8ad-4eb9-a986-c4996db8829f' User entered '23 Aug 2020 15:25'	System	23 Aug 2020 22:25:15
	System	23 Aug 2020 22:25:15

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 7'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:18', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c4e9befd-9830-4f3d-92dc-7ccc63dc6248'	System	24 Aug 2020 23:38:33
User entered 'None (1)'	System	24 Aug 2020 23:38:33

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:20', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c4e9befd-9830-4f3d-92dc-7ccc63dc6248'	System	24 Aug 2020 23:38:33
User entered 'No (N)'	System	24 Aug 2020 23:38:33

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c4e9befd-9830-4f3d-92dc-7ccc63dc6248'	System	24 Aug 2020 23:38:33
User entered 'No (N)'	System	24 Aug 2020 23:38:33

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:25', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c4e9befd-9830-4f3d-92dc-7ccc63dc6248'	System	24 Aug 2020 23:38:33
User entered 'None (1)'	System	24 Aug 2020 23:38:33

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c4e9befd-9830-4f3d-92dc-7ccc63dc6248' User entered '24 Aug 2020 16:38'	System	24 Aug 2020 23:38:33
	System	24 Aug 2020 23:38:33

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:06:40', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'None (0)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:06:58', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'None (0)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:07:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'None (0)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:07:03', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'None (0)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:07:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'None (0)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:07:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'None (0)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:07:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered 'No (N)'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T15:07:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dc757f2f-06be-4420-9dec-2df8332cdf9e' User entered '18 Aug 2020 15:07'	System	18 Aug 2020 22:07:25
	System	18 Aug 2020 22:07:25

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 14:51'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 17:21'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'None (0)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'None (0)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'None (0)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'None (0)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'None (0)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'None (0)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:23:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0' User entered 'No (N)'	System	19 Aug 2020 01:24:23
	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-18T18:24:21', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '7c8d5aee-90bb-4acb-be3b-144396d845a0'	System	19 Aug 2020 01:24:23
User entered '18 Aug 2020 18:24'	System	19 Aug 2020 01:24:23

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Aug 2020 18:16'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 2'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'None (0)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'None (0)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'None (0)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'None (0)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:36', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'None (0)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'None (0)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:46', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered 'No (N)'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-20T04:42:52', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33e89acf-de57-45b1-9575-ccad06ed63a5' User entered '20 Aug 2020 04:42'	System	20 Aug 2020 11:42:54
	System	20 Aug 2020 11:42:54

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 3'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:20:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered 'None (0)'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:20:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered 'No interference with activity (1)'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:20:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered 'None (0)'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:20:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered 'None (0)'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered 'None (0)'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:04', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293' User entered 'None (0)'	System	21 Aug 2020 13:21:19
	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered 'No (N)'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T06:21:17', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b8f72da5-1d98-4d93-bf00-328791f61293'	System	21 Aug 2020 13:21:19
User entered '21 Aug 2020 06:21'	System	21 Aug 2020 13:21:19

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 4'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968'	System	22 Aug 2020 02:34:47
User entered 'None (0)'	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:26', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968'	System	22 Aug 2020 02:34:47
User entered 'None (0)'	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:28', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968'	System	22 Aug 2020 02:34:47
User entered 'None (0)'	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968' User entered 'None (0)'	System	22 Aug 2020 02:34:47
	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:32', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968'	System	22 Aug 2020 02:34:47
User entered 'None (0)'	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968' User entered 'None (0)'	System	22 Aug 2020 02:34:47
	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:36', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968'	System	22 Aug 2020 02:34:47
User entered 'No (N)'	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-21T19:34:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf86c0d9-8f54-4d3c-8f8e-96d14adc5968'	System	22 Aug 2020 02:34:47
User entered '21 Aug 2020 19:34'	System	22 Aug 2020 02:34:47

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 5'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'None (0)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:11', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'None (0)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:14', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'None (0)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:17', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'None (0)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:21', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'None (0)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'None (0)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294' User entered 'No (N)'	System	23 Aug 2020 09:23:39
	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T02:23:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31b8d9bf-bcd3-4099-a38c-82ada800f294'	System	23 Aug 2020 09:23:39
User entered '23 Aug 2020 02:23'	System	23 Aug 2020 09:23:39

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 6'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered 'None (0)'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:14', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered 'None (0)'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered 'None (0)'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:18', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered 'None (0)'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8'	System	23 Aug 2020 21:58:42
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered 'None (0)'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered 'No (N)'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-23T14:58:40', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a0ae4f96-3a18-43cd-8db2-8a96ac5524a8' User entered '23 Aug 2020 14:58'	System	23 Aug 2020 21:58:42
	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 7'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98' User entered 'None (0)'	System	24 Aug 2020 23:39:00
	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:36', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98' User entered 'None (0)'	System	24 Aug 2020 23:39:00
	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98' User entered 'None (0)'	System	24 Aug 2020 23:39:00
	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:40', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98' User entered 'None (0)'	System	24 Aug 2020 23:39:00
	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98'	System	24 Aug 2020 23:39:00
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98' User entered 'None (0)'	System	24 Aug 2020 23:39:00
	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:50', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98'	System	24 Aug 2020 23:39:00
User entered 'No (N)'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-24T16:38:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8bdcd187-4d12-4ca8-b8d3-df2d71afaa98'	System	24 Aug 2020 23:39:00
User entered '24 Aug 2020 16:38'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	23 Aug 2020 21:58:42
User entered 'Day 8'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:29:49

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-25T16:41:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '40830ed7-7f5b-4c46-b96e-e30a0d0b5704'	System	25 Aug 2020 23:41:44
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-25T16:41:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '40830ed7-7f5b-4c46-b96e-e30a0d0b5704' User entered '25 Aug 2020 16:41'	System	25 Aug 2020 23:41:44
	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	24 Aug 2020 23:39:00
User entered 'Day 9'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:29:49

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-26T21:36:19', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4a6c96df-2b49-4883-816a-b87a6e733f2c'	System	27 Aug 2020 04:36:26
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-26T21:36:23', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4a6c96df-2b49-4883-816a-b87a6e733f2c' User entered '26 Aug 2020 21:36'	System	27 Aug 2020 04:36:26
	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(9)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	25 Aug 2020 23:41:44
User entered 'Day 10'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:29:49

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-27T13:18:55', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0cb3370c-7f64-44fa-9468-75b46000b981'	System	27 Aug 2020 20:19:04
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-27T13:19:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0cb3370c-7f64-44fa-9468-75b46000b981' User entered '27 Aug 2020 13:19'	System	27 Aug 2020 20:19:04
	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(10)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	27 Aug 2020 04:36:26
User entered 'Day 11'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:29:49

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-28T16:00:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e0ccf561-0164-4411-b39b-443554a96fc8'	System	28 Aug 2020 23:00:47
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	28 Aug 2020 23:00:47

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-28T16:00:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e0ccf561-0164-4411-b39b-443554a96fc8'	System	28 Aug 2020 23:00:47
User entered '28 Aug 2020 16:00'	System	28 Aug 2020 23:00:47

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(11)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	27 Aug 2020 20:19:04
User entered 'Day 12'	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 15:29:49

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-30T07:07:21', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a442b940-1723-40d9-926f-05b8c5aa317b' User entered 'None (0)'	System	30 Aug 2020 14:07:31
	System	30 Aug 2020 14:07:31

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-30T07:07:28', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a442b940-1723-40d9-926f-05b8c5aa317b' User entered '30 Aug 2020 07:07'	System	30 Aug 2020 14:07:31
	System	30 Aug 2020 14:07:31

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Nausea_Day(12)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	23 Aug 2020 21:58:42
User entered 'Day 8'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-25T16:41:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8d03c36e-e798-4a66-9a22-5980bb7f7f6b' User entered 'No (N)'	System	25 Aug 2020 23:41:52
	System	25 Aug 2020 23:41:52

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-25T16:41:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8d03c36e-e798-4a66-9a22-5980bb7f7f6b' User entered '25 Aug 2020 16:41'	System	25 Aug 2020 23:41:52
	System	25 Aug 2020 23:41:52

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '25 Aug 2020 12:00'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '26 Aug 2020 11:59'	System	23 Aug 2020 21:58:42

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	24 Aug 2020 23:39:00
User entered 'Day 9'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-26T21:36:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cd07d0c2-c1f5-45be-aecb-1b405d5b889b' User entered 'No (N)'	System	27 Aug 2020 04:36:37
	System	27 Aug 2020 04:36:37

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-26T21:36:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cd07d0c2-c1f5-45be-aecb-1b405d5b889b' User entered '26 Aug 2020 21:36'	System	27 Aug 2020 04:36:37
	System	27 Aug 2020 04:36:37

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '26 Aug 2020 12:00'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '27 Aug 2020 11:59'	System	24 Aug 2020 23:39:00

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	25 Aug 2020 23:41:44
User entered 'Day 10'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-27T13:19:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '118ba936-54a9-49a2-a8cf-86f98f0af348' User entered 'No (N)'	System	27 Aug 2020 20:19:10
	System	27 Aug 2020 20:19:10

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-27T13:19:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '118ba936-54a9-49a2-a8cf-86f98f0af348'	System	27 Aug 2020 20:19:10
User entered '27 Aug 2020 13:19'	System	27 Aug 2020 20:19:10

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(10)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 23:41:44

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	27 Aug 2020 04:36:26
User entered 'Day 11'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-28T16:00:53', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ec5f140e-4fec-4c9b-bc8f-210e5a70fea2'	System	28 Aug 2020 23:01:01
User entered 'No (N)'	System	28 Aug 2020 23:01:01

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-28T16:00:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'ec5f140e-4fec-4c9b-bc8f-210e5a70fea2'	System	28 Aug 2020 23:01:01
User entered '28 Aug 2020 16:00'	System	28 Aug 2020 23:01:01

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(11)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 04:36:26

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	27 Aug 2020 20:19:04
User entered 'Day 12'	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-30T07:07:32', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '872114f8-e9df-4f04-bfd0-6ad83def1c19'	System	30 Aug 2020 14:08:59
User entered 'No (N)'	System	30 Aug 2020 14:08:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-08-30T07:07:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '872114f8-e9df-4f04-bfd0-6ad83def1c19'	System	30 Aug 2020 14:08:59
User entered '30 Aug 2020 07:07'	System	30 Aug 2020 14:08:59

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 20:19:04

US3162139

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(12)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 20:19:04

US3162139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Aug 2020 18:44:14
	(b) (4)	

US3162139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '25 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 18:44:14

US3162139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Contact Made (CONTACT MADE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 18:44:14

US3162139

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 18:44:14

US3162139

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	28 Aug 2020 18:44:35
	(b) (4)	

US3162139

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	28 Aug 2020 18:44:35

US3162139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 02:53:20

US3162139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '1 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 02:53:20

US3162139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 02:53:20

US3162139

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 02:53:20

US3162139

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	02 Sep 2020 02:53:28

US3162139

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	02 Sep 2020 02:53:28

US3162139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 04:04:51

US3162139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '8 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 04:04:51

US3162139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 04:04:51

US3162139

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 04:04:51

US3162139

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	09 Sep 2020 04:04:54

US3162139

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	09 Sep 2020 04:04:54

US3162139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 18:59:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4)	16 Sep 2020 18:59:30
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4)	16 Sep 2020 18:59:30
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'VISIT2'	System	16 Sep 2020 18:59:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User accepted default value 'Pre-Dose (PREDOSE)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:01:43
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:01:43
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '12:47'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:01:43
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '15 Sep 2020 12:47'	System	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '37.3' C	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	16 Sep 2020 19:01:43
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '74'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'bpm'	System	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '12'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'breaths/min'	System	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '140'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '78'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	16 Sep 2020 19:01:43

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User accepted default value 'Post-Dose (POSTDOSE)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:02:23
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '14:36'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:02:23
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '15 Sep 2020 14:36'	System	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '36.9' C	Cynthia Kunakom (b) (4)	16 Sep 2020 19:02:23
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '75'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'bpm'	System	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '14'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'breaths/min'	System	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '143'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '91'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	16 Sep 2020 19:02:23

US3162139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:02:34
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:02:34
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jourdan Manfred (b) (4) (b) (4)	15 Sep 2020 21:01:12

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered empty.	Jourdan Manfred (b) (4)	15 Sep 2020 21:01:12
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jourdan Manfred (b) (4) (b) (4)	15 Sep 2020 21:01:12

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'MRNA-1273 OR PLACEBO'	System	15 Sep 2020 21:01:12

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '15 Sep 2020'	Jourdan Manfred (b) (4)	15 Sep 2020 21:01:12
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '13:57'	Jourdan Manfred (b) (4)	15 Sep 2020 21:01:12
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '15 Sep 2020 13:57'	System	15 Sep 2020 21:01:12

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Jourdan Manfred (b) (4)	15 Sep 2020 21:01:12
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'ONCE'	System	15 Sep 2020 21:01:12

US3162139

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'INTRAMUSCULAR'	System	15 Sep 2020 21:01:12

US3162139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:03:21

US3162139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:03:21

US3162139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '13:25'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:03:21

US3162139

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '15 Sep 2020 13:25'	System	16 Sep 2020 19:03:21

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '15 Sep 2020'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '13:27'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:03:30
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '15 Sep 2020 13:27'	System	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Cynthia Kunakom (b) (4)	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	16 Sep 2020 19:03:30
	(b) (4)	

US3162139

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered empty.	System	16 Sep 2020 19:03:30

US3162139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	16 Sep 2020 18:41:10

US3162139

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'I'	System	16 Sep 2020 18:41:10

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:31:21', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '574d7fe4-0bfd-44ea-a9a7-0aaed142fe13' User entered 'Yes (Y)'	System	15 Sep 2020 21:31:46
	System	15 Sep 2020 21:31:46

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:31:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '574d7fe4-0bfd-44ea-a9a7-0aaed142fe13' User entered '98.4'	System	15 Sep 2020 21:31:46
	System	15 Sep 2020 21:31:46

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:31:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '574d7fe4-0bfd-44ea-a9a7-0aaed142fe13'	System	15 Sep 2020 21:31:46
User entered 'No (N)'	System	15 Sep 2020 21:31:46

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:31:44', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '574d7fe4-0bfd-44ea-a9a7-0aaed142fe13'	System	15 Sep 2020 21:31:46
User entered '15 Sep 2020 14:31'	System	15 Sep 2020 21:31:46

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 14:17'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 16:47'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6159a430-cd1b-4c99-8f39-79e1cc60e719' User entered 'Yes (Y)'	System	16 Sep 2020 02:38:28
	System	16 Sep 2020 02:38:28

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6159a430-cd1b-4c99-8f39-79e1cc60e719' User entered '96.9'	System	16 Sep 2020 02:38:28
	System	16 Sep 2020 02:38:28

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6159a430-cd1b-4c99-8f39-79e1cc60e719'	System	16 Sep 2020 02:38:28
User entered 'No (N)'	System	16 Sep 2020 02:38:28

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:26', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6159a430-cd1b-4c99-8f39-79e1cc60e719'	System	16 Sep 2020 02:38:28
User entered '15 Sep 2020 19:38'	System	16 Sep 2020 02:38:28

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 17:42'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 2'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1ced8ad5-8ba8-45af-9db8-8c16f8a340e4' User entered 'Yes (Y)'	System	17 Sep 2020 01:15:26
	System	17 Sep 2020 01:15:26

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1ced8ad5-8ba8-45af-9db8-8c16f8a340e4' User entered '98.3'	System	17 Sep 2020 01:15:26
	System	17 Sep 2020 01:15:26

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:18', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1ced8ad5-8ba8-45af-9db8-8c16f8a340e4'	System	17 Sep 2020 01:15:26
User entered 'No (N)'	System	17 Sep 2020 01:15:26

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:23', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1ced8ad5-8ba8-45af-9db8-8c16f8a340e4'	System	17 Sep 2020 01:15:26
User entered '16 Sep 2020 18:15'	System	17 Sep 2020 01:15:26

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 3'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4435778d-0466-4ef3-96bf-6d5fa0df2c58'	System	18 Sep 2020 15:04:30
User entered 'Yes (Y)'	System	18 Sep 2020 15:04:30

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:20', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4435778d-0466-4ef3-96bf-6d5fa0df2c58' User entered '98.1'	System	18 Sep 2020 15:04:30
	System	18 Sep 2020 15:04:30

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:23', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4435778d-0466-4ef3-96bf-6d5fa0df2c58'	System	18 Sep 2020 15:04:30
User entered 'No (N)'	System	18 Sep 2020 15:04:30

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4435778d-0466-4ef3-96bf-6d5fa0df2c58'	System	18 Sep 2020 15:04:30
User entered '18 Sep 2020 08:04'	System	18 Sep 2020 15:04:30

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 4'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:51:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b6e30df9-5f25-4827-8a82-3a3c5a7847bb' User entered 'Yes (Y)'	System	19 Sep 2020 02:51:35
	System	19 Sep 2020 02:51:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:51:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b6e30df9-5f25-4827-8a82-3a3c5a7847bb' User entered '97.3'	System	19 Sep 2020 02:51:35
	System	19 Sep 2020 02:51:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:51:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b6e30df9-5f25-4827-8a82-3a3c5a7847bb'	System	19 Sep 2020 02:51:35
User entered 'No (N)'	System	19 Sep 2020 02:51:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:51:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b6e30df9-5f25-4827-8a82-3a3c5a7847bb' User entered '18 Sep 2020 19:51'	System	19 Sep 2020 02:51:35
	System	19 Sep 2020 02:51:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 5'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '9b6af802-1949-44ef-ab95-8cda8cf510a5'	System	20 Sep 2020 02:42:23
User entered 'Yes (Y)'	System	20 Sep 2020 02:42:23

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '9b6af802-1949-44ef-ab95-8cda8cf510a5' User entered '97.8'	System	20 Sep 2020 02:42:23
	System	20 Sep 2020 02:42:23

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:17', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '9b6af802-1949-44ef-ab95-8cda8cf510a5'	System	20 Sep 2020 02:42:23
User entered 'No (N)'	System	20 Sep 2020 02:42:23

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:20', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '9b6af802-1949-44ef-ab95-8cda8cf510a5' User entered '19 Sep 2020 19:42'	System	20 Sep 2020 02:42:23
	System	20 Sep 2020 02:42:23

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 6'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:24:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e75cd300-0ec8-400a-b8e2-2ae343bca713' User entered 'Yes (Y)'	System	20 Sep 2020 23:25:35
	System	20 Sep 2020 23:25:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:24:55', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e75cd300-0ec8-400a-b8e2-2ae343bca713' User entered '98.1'	System	20 Sep 2020 23:25:35
	System	20 Sep 2020 23:25:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e75cd300-0ec8-400a-b8e2-2ae343bca713'	System	20 Sep 2020 23:25:35
User entered 'Yes (Y)'	System	20 Sep 2020 23:25:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Per day 36 phone call, subject took acetaminophen 500 mg for chronic right knee pain.' (Site from System).	(b) (4)	30 Sep 2020 19:30:29
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Judith Kirstein (b) (4)	22 Sep 2020 22:26:25
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:19', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e75cd300-0ec8-400a-b8e2-2ae343bca713'	(b) (4)	
User entered '1'	System	20 Sep 2020 23:25:35
	System	20 Sep 2020 23:25:35
	System	20 Sep 2020 23:25:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:19', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e75cd300-0ec8-400a-b8e2-2ae343bca713' User entered '0'	System	20 Sep 2020 23:25:35
	System	20 Sep 2020 23:25:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e75cd300-0ec8-400a-b8e2-2ae343bca713'	System	20 Sep 2020 23:25:35
User entered '20 Sep 2020 16:25'	System	20 Sep 2020 23:25:35

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 7'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:23:11', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4fb48562-f7c8-447b-8aab-f4c05a7e1bd6'	System	22 Sep 2020 00:23:38
User entered 'Yes (Y)'	System	22 Sep 2020 00:23:38

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:23:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4fb48562-f7c8-447b-8aab-f4c05a7e1bd6'	System	22 Sep 2020 00:23:38
User entered '98.2'	System	22 Sep 2020 00:23:38

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:23:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4fb48562-f7c8-447b-8aab-f4c05a7e1bd6'	System	22 Sep 2020 00:23:38
User entered 'No (N)'	System	22 Sep 2020 00:23:38

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:23:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4fb48562-f7c8-447b-8aab-f4c05a7e1bd6'	System	22 Sep 2020 00:23:38
User entered '21 Sep 2020 17:23'	System	22 Sep 2020 00:23:38

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:29:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd7170ea1-fdea-4fa1-bd65-3b5d4adf4f13'	System	15 Sep 2020 21:30:08
User entered 'None (1)'	System	15 Sep 2020 21:30:08

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:29:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd7170ea1-fdea-4fa1-bd65-3b5d4adf4f13' User entered 'No (N)'	System	15 Sep 2020 21:30:08
	System	15 Sep 2020 21:30:08

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:29:48', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd7170ea1-fdea-4fa1-bd65-3b5d4adf4f13' User entered 'No (N)'	System	15 Sep 2020 21:30:08
	System	15 Sep 2020 21:30:08

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:29:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd7170ea1-fdea-4fa1-bd65-3b5d4adf4f13'	System	15 Sep 2020 21:30:08
User entered 'None (1)'	System	15 Sep 2020 21:30:08

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd7170ea1-fdea-4fa1-bd65-3b5d4adf4f13'	System	15 Sep 2020 21:30:08
User entered '15 Sep 2020 14:30'	System	15 Sep 2020 21:30:08

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 14:17'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 16:47'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'af9e4dd8-4416-4b41-8a85-a59f88736c50'	System	16 Sep 2020 02:38:51
User entered 'None (1)'	System	16 Sep 2020 02:38:51

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'af9e4dd8-4416-4b41-8a85-a59f88736c50'	System	16 Sep 2020 02:38:51
User entered 'No (N)'	System	16 Sep 2020 02:38:51

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'af9e4dd8-4416-4b41-8a85-a59f88736c50' User entered 'No (N)'	System	16 Sep 2020 02:38:51
	System	16 Sep 2020 02:38:51

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:44', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'af9e4dd8-4416-4b41-8a85-a59f88736c50'	System	16 Sep 2020 02:38:51
User entered 'None (1)'	System	16 Sep 2020 02:38:51

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'af9e4dd8-4416-4b41-8a85-a59f88736c50'	System	16 Sep 2020 02:38:51
User entered '15 Sep 2020 19:38'	System	16 Sep 2020 02:38:51

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 17:42'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 2'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '97ede2ec-524b-4d18-ada3-15e5efe4c28f' User entered 'None (1)'	System	17 Sep 2020 01:15:58
	System	17 Sep 2020 01:15:58

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:32', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '97ede2ec-524b-4d18-ada3-15e5efe4c28f' User entered 'No (N)'	System	17 Sep 2020 01:15:58
	System	17 Sep 2020 01:15:58

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '97ede2ec-524b-4d18-ada3-15e5efe4c28f' User entered 'No (N)'	System	17 Sep 2020 01:15:58
	System	17 Sep 2020 01:15:58

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '97ede2ec-524b-4d18-ada3-15e5efe4c28f' User entered 'None (1)'	System	17 Sep 2020 01:15:58
	System	17 Sep 2020 01:15:58

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '97ede2ec-524b-4d18-ada3-15e5efe4c28f' User entered '16 Sep 2020 18:15'	System	17 Sep 2020 01:15:58
	System	17 Sep 2020 01:15:58

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 3'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:32', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33157bea-d666-4365-ac4b-d85f5b923b6c' User entered 'None (1)'	System	18 Sep 2020 15:04:55
	System	18 Sep 2020 15:04:55

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:36', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33157bea-d666-4365-ac4b-d85f5b923b6c' User entered 'No (N)'	System	18 Sep 2020 15:04:55
	System	18 Sep 2020 15:04:55

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:39', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33157bea-d666-4365-ac4b-d85f5b923b6c' User entered 'No (N)'	System	18 Sep 2020 15:04:55
	System	18 Sep 2020 15:04:55

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33157bea-d666-4365-ac4b-d85f5b923b6c' User entered 'None (1)'	System	18 Sep 2020 15:04:55
	System	18 Sep 2020 15:04:55

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:52', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '33157bea-d666-4365-ac4b-d85f5b923b6c' User entered '18 Sep 2020 08:04'	System	18 Sep 2020 15:04:55
	System	18 Sep 2020 15:04:55

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 4'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aef3e6d9-6bbb-45dc-bdfd-1a8219de254e'	System	19 Sep 2020 02:50:39
User entered 'None (1)'	System	19 Sep 2020 02:50:39

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:26', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aef3e6d9-6bbb-45dc-bdfd-1a8219de254e' User entered 'No (N)'	System	19 Sep 2020 02:50:39
	System	19 Sep 2020 02:50:39

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aef3e6d9-6bbb-45dc-bdfd-1a8219de254e' User entered 'No (N)'	System	19 Sep 2020 02:50:39
	System	19 Sep 2020 02:50:39

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aef3e6d9-6bbb-45dc-bdfd-1a8219de254e' User entered 'None (1)'	System	19 Sep 2020 02:50:39
	System	19 Sep 2020 02:50:39

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aef3e6d9-6bbb-45dc-bdfd-1a8219de254e'	System	19 Sep 2020 02:50:39
User entered '18 Sep 2020 19:50'	System	19 Sep 2020 02:50:39

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 5'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58467898-5c37-4ccf-9275-4287e5c3d95b' User entered 'None (1)'	System	20 Sep 2020 02:42:37
	System	20 Sep 2020 02:42:37

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:27', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58467898-5c37-4ccf-9275-4287e5c3d95b' User entered 'No (N)'	System	20 Sep 2020 02:42:37
	System	20 Sep 2020 02:42:37

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:29', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58467898-5c37-4ccf-9275-4287e5c3d95b' User entered 'No (N)'	System	20 Sep 2020 02:42:37
	System	20 Sep 2020 02:42:37

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58467898-5c37-4ccf-9275-4287e5c3d95b' User entered 'None (1)'	System	20 Sep 2020 02:42:37
	System	20 Sep 2020 02:42:37

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '58467898-5c37-4ccf-9275-4287e5c3d95b' User entered '19 Sep 2020 19:42'	System	20 Sep 2020 02:42:37
	System	20 Sep 2020 02:42:37

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 6'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '982a72bd-6ce5-4b2b-814c-1d0b6d9def02'	System	20 Sep 2020 23:25:57
User entered 'None (1)'	System	20 Sep 2020 23:25:57

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:40', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '982a72bd-6ce5-4b2b-814c-1d0b6d9def02'	System	20 Sep 2020 23:25:57
User entered 'No (N)'	System	20 Sep 2020 23:25:57

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:43', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '982a72bd-6ce5-4b2b-814c-1d0b6d9def02' User entered 'No (N)'	System	20 Sep 2020 23:25:57
	System	20 Sep 2020 23:25:57

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '982a72bd-6ce5-4b2b-814c-1d0b6d9def02'	System	20 Sep 2020 23:25:57
User entered 'None (1)'	System	20 Sep 2020 23:25:57

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '982a72bd-6ce5-4b2b-814c-1d0b6d9def02' User entered '20 Sep 2020 16:25'	System	20 Sep 2020 23:25:57
	System	20 Sep 2020 23:25:57

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 7'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dcc92b10-0311-4290-b12d-7ec25ffa975a'	System	22 Sep 2020 00:22:35
User entered 'None (1)'	System	22 Sep 2020 00:22:35

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:19', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dcc92b10-0311-4290-b12d-7ec25ffa975a'	System	22 Sep 2020 00:22:35
User entered 'No (N)'	System	22 Sep 2020 00:22:35

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:24', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dcc92b10-0311-4290-b12d-7ec25ffa975a'	System	22 Sep 2020 00:22:35
User entered 'No (N)'	System	22 Sep 2020 00:22:35

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:28', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dcc92b10-0311-4290-b12d-7ec25ffa975a'	System	22 Sep 2020 00:22:35
User entered 'None (1)'	System	22 Sep 2020 00:22:35

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:32', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'dcc92b10-0311-4290-b12d-7ec25ffa975a' User entered '21 Sep 2020 17:22'	System	22 Sep 2020 00:22:35
	System	22 Sep 2020 00:22:35

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:11', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351' User entered 'None (0)'	System	15 Sep 2020 21:31:08
	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:14', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351' User entered 'None (0)'	System	15 Sep 2020 21:31:08
	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:17', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351' User entered 'None (0)'	System	15 Sep 2020 21:31:08
	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:22', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351' User entered 'None (0)'	System	15 Sep 2020 21:31:08
	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:26', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351' User entered 'None (0)'	System	15 Sep 2020 21:31:08
	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:28', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351' User entered 'None (0)'	System	15 Sep 2020 21:31:08
	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:30', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351'	System	15 Sep 2020 21:31:08
User entered 'No (N)'	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T14:30:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '68655730-4953-4119-9442-a3b1d14f0351'	System	15 Sep 2020 21:31:08
User entered '15 Sep 2020 14:30'	System	15 Sep 2020 21:31:08

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 14:17'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 16:47'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 1, after vaccination (at home)'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:55', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'None (0)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:38:57', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'None (0)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:39:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'None (0)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:39:04', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'None (0)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:39:07', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'None (0)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:39:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'None (0)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:39:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered 'No (N)'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-15T19:39:19', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b40b4d8c-ac9c-4097-a5e2-37d0f5107fe8' User entered '15 Sep 2020 19:39'	System	16 Sep 2020 02:39:20
	System	16 Sep 2020 02:39:20

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '15 Sep 2020 17:42'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '16 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 2'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72' User entered 'None (0)'	System	17 Sep 2020 01:16:19
	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:15:58', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72' User entered 'None (0)'	System	17 Sep 2020 01:16:19
	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:16:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72' User entered 'None (0)'	System	17 Sep 2020 01:16:19
	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:16:02', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72' User entered 'None (0)'	System	17 Sep 2020 01:16:19
	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:16:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72' User entered 'None (0)'	System	17 Sep 2020 01:16:19
	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:16:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72' User entered 'None (0)'	System	17 Sep 2020 01:16:19
	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:16:11', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72'	System	17 Sep 2020 01:16:19
User entered 'No (N)'	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-16T18:16:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6f6ec4e8-352f-4fce-a78b-61d0d9ccdb72'	System	17 Sep 2020 01:16:19
User entered '16 Sep 2020 18:16'	System	17 Sep 2020 01:16:19

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '16 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '17 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 3'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:57', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'None (0)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:04:59', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'None (0)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:05:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'None (0)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:05:03', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'None (0)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:05:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'None (0)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:05:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'None (0)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:05:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered 'No (N)'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T08:05:13', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '0a9800b8-80d8-4fe5-9c27-d6cd0e59daf6' User entered '18 Sep 2020 08:05'	System	18 Sep 2020 15:05:16
	System	18 Sep 2020 15:05:16

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '17 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 4'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:49:53', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered 'None (0)'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:49:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered 'None (0)'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:49:58', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered 'None (0)'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:04', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered 'None (0)'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered 'None (0)'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered 'None (0)'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:13', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929'	System	19 Sep 2020 02:50:22
User entered 'No (N)'	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-18T19:50:20', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'caa5a30e-5897-45b4-807d-a7d086d17929' User entered '18 Sep 2020 19:50'	System	19 Sep 2020 02:50:22
	System	19 Sep 2020 02:50:22

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '18 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 5'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'None (0)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:44', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'None (0)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'None (0)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'None (0)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:50', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'None (0)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:54', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'None (0)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:42:57', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered 'No (N)'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-19T19:43:02', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'b87c6021-48ce-44ce-b50d-936175434a81' User entered '19 Sep 2020 19:43'	System	20 Sep 2020 02:43:05
	System	20 Sep 2020 02:43:05

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '19 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 6'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:54', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered 'None (0)'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:25:56', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered 'None (0)'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:26:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered 'None (0)'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:26:10', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered 'None (0)'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:26:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered 'None (0)'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:26:14', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered 'None (0)'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:26:17', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2'	System	20 Sep 2020 23:26:21
User entered 'No (N)'	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-20T16:26:20', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '242326b0-f0cc-4ce6-94d2-d6be7a79fcc2' User entered '20 Sep 2020 16:26'	System	20 Sep 2020 23:26:21
	System	20 Sep 2020 23:26:21

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '20 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	15 Sep 2020 21:01:12
User entered 'Day 7'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:36', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'None (0)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'None (0)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'None (0)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:47', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'None (0)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'None (0)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:52', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'None (0)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:55', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered 'No (N)'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-09-21T17:22:59', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'fabdcf1c-2f16-434c-bb48-19e87cdafb2d' User entered '21 Sep 2020 17:22'	System	22 Sep 2020 00:23:03
	System	22 Sep 2020 00:23:03

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '21 Sep 2020 12:00'	System	15 Sep 2020 21:01:12

US3162139

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:29:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
User entered '22 Sep 2020 11:59'	System	15 Sep 2020 21:01:12

US3162139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:08:47

US3162139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '22 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:08:47

US3162139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:08:47

US3162139

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:08:47

US3162139

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:08:55

US3162139

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	22 Sep 2020 21:08:55

US3162139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:21:39

US3162139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '29 Sep 2020'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:21:39

US3162139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:21:39

US3162139

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:21:39

US3162139

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	30 Sep 2020 04:21:42

US3162139

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	30 Sep 2020 04:21:42

US3162139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 08:58:44
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Not missing in EDC' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	21 Oct 2020 19:21:27
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	21 Oct 2020 10:57:46
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 01:55:07

US3162139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '6 Oct 2020'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 01:55:07

US3162139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Contact Made (CONTACT MADE)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 01:55:07

US3162139

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 01:55:07

US3162139

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	07 Oct 2020 01:55:11

US3162139

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	07 Oct 2020 01:55:11

US3162139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:25

US3162139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '12 Oct 2020'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:16:25
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:16:25
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'VISIT3'	System	21 Oct 2020 19:16:25

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '12 Oct 2020'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:16:56
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '9:23'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:16:56
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '12 Oct 2020 9:23'	System	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '37' C	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '71'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:16:56
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'bpm'	System	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '14'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'breaths/min'	System	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '144'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '83'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'mmHg'	System	21 Oct 2020 19:16:56

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51

US3162139

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51

US3162139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:17:08
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:17:08
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:17:17

US3162139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '12 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:17:17

US3162139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered '9:38'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:17:17

US3162139

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered '12 Oct 2020 9:38'	System	21 Oct 2020 19:17:17

US3162139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:17:21
	(b) (4)	

US3162139

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:51
User entered 'I'	System	21 Oct 2020 19:17:21

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 64'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:20', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered 'Yes (Y)'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:26', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered 'No (N)'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:32', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered 'Yes (Y)'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '1'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '1'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '1'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '1'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:51', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '0'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Please 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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:52:59', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e'	System	18 Oct 2020 15:53:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:53:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e'	System	18 Oct 2020 15:53:52
User entered 'Yes (Y)'	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Please 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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:53:16', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e'	System	18 Oct 2020 15:53:52
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-18T08:53:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '31812289-43a6-43f6-986b-b543c362774e' User entered '18 Oct 2020 08:53:41'	System	18 Oct 2020 15:53:52
	System	18 Oct 2020 15:53:52

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 71'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-26T07:40:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aaefb011-a5d2-4014-8f3a-95e595dc8329'	System	26 Oct 2020 14:40:33
User entered 'No (N)'	System	26 Oct 2020 14:40:33

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-26T07:39:53', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aaefb011-a5d2-4014-8f3a-95e595dc8329'	System	26 Oct 2020 14:40:33
User entered 'No (N)'	System	26 Oct 2020 14:40:33

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-10-26T07:40:28', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'aaefb011-a5d2-4014-8f3a-95e595dc8329' User entered '26 Oct 2020 07:40:28'	System	26 Oct 2020 14:40:33
	System	26 Oct 2020 14:40:33

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 78'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-01T07:29:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '99c67afd-37be-4d40-b010-0fd394cd34ae' User entered 'No (N)'	System	01 Nov 2020 15:30:08
	System	01 Nov 2020 15:30:08

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-01T07:29:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '99c67afd-37be-4d40-b010-0fd394cd34ae'	System	01 Nov 2020 15:30:08
User entered 'No (N)'	System	01 Nov 2020 15:30:08

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-01T07:30:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '99c67afd-37be-4d40-b010-0fd394cd34ae' User entered '01 Nov 2020 07:30:06'	System	01 Nov 2020 15:30:08
	System	01 Nov 2020 15:30:08

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered 'Day 92'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-15T07:43:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '23e076ee-fef5-47e9-a819-78488f26b851'	System	15 Nov 2020 15:43:53
User entered 'No (N)'	System	15 Nov 2020 15:43:53

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-15T07:43:44', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '23e076ee-fef5-47e9-a819-78488f26b851'	System	15 Nov 2020 15:43:53
User entered 'No (N)'	System	15 Nov 2020 15:43:53

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-15T07:43:50', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '23e076ee-fef5-47e9-a819-78488f26b851' User entered '15 Nov 2020 07:43:50'	System	15 Nov 2020 15:43:53
	System	15 Nov 2020 15:43:53

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 21:45:40

US3162139

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 04:56:08
Data entry locked.	System	18 Aug 2020 21:45:40
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 21:45:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-22T05:43:23', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '01aa2f6f-de21-466f-9de9-0117ba2d6caf'	System	22 Nov 2020 13:43:48
User entered 'No (N)'	System	22 Nov 2020 13:43:48

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-22T05:43:35', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '01aa2f6f-de21-466f-9de9-0117ba2d6caf'	System	22 Nov 2020 13:43:48
User entered 'No (N)'	System	22 Nov 2020 13:43:48

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-22T05:43:45', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '01aa2f6f-de21-466f-9de9-0117ba2d6caf' User entered '22 Nov 2020 05:43:45'	System	22 Nov 2020 13:43:48
	System	22 Nov 2020 13:43:48

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-26T12:24:59', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '35bfd6a5-46b5-4bbb-8f85-dfe83fb13c54'	System	26 Nov 2020 20:25:22
User entered 'No (N)'	System	26 Nov 2020 20:25:22

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-26T12:25:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '35bfd6a5-46b5-4bbb-8f85-dfe83fb13c54'	System	26 Nov 2020 20:25:22
User entered 'No (N)'	System	26 Nov 2020 20:25:22

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-11-26T12:25:14', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '35bfd6a5-46b5-4bbb-8f85-dfe83fb13c54' User entered '26 Nov 2020 12:25:14'	System	26 Nov 2020 20:25:22
	System	26 Nov 2020 20:25:22

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-04T12:50:58', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e0aff10a-3810-4f66-93cb-a49052dd353b'	System	04 Dec 2020 20:51:09
User entered 'No (N)'	System	04 Dec 2020 20:51:09

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-04T12:51:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e0aff10a-3810-4f66-93cb-a49052dd353b'	System	04 Dec 2020 20:51:09
User entered 'No (N)'	System	04 Dec 2020 20:51:09

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-04T12:51:06', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'e0aff10a-3810-4f66-93cb-a49052dd353b' User entered '04 Dec 2020 12:51:06'	System	04 Dec 2020 20:51:09
	System	04 Dec 2020 20:51:09

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-10T08:43:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8de04732-0fcd-4b73-bfcf-0b4ca324b553'	System	10 Dec 2020 16:43:56
User entered 'No (N)'	System	10 Dec 2020 16:43:56

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-10T08:43:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8de04732-0fcd-4b73-bfcf-0b4ca324b553'	System	10 Dec 2020 16:43:56
User entered 'No (N)'	System	10 Dec 2020 16:43:56

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-10T08:43:54', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8de04732-0fcd-4b73-bfcf-0b4ca324b553' User entered '10 Dec 2020 08:43:54'	System	10 Dec 2020 16:43:56
	System	10 Dec 2020 16:43:56

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-18T10:14:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd1bbc2ed-19f7-405d-923d-8b77d5dab90d'	System	18 Dec 2020 18:14:38
User entered 'No (N)'	System	18 Dec 2020 18:14:38

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-18T10:14:10', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd1bbc2ed-19f7-405d-923d-8b77d5dab90d'	System	18 Dec 2020 18:14:38
User entered 'No (N)'	System	18 Dec 2020 18:14:38

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-18T10:14:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'd1bbc2ed-19f7-405d-923d-8b77d5dab90d'	System	18 Dec 2020 18:14:38
User entered '18 Dec 2020 10:14:33'	System	18 Dec 2020 18:14:38

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-26T09:37:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '48c42d05-7fec-4c3b-8e3b-bd3c6fdb897c' User entered 'No (N)'	System	26 Dec 2020 17:37:15
	System	26 Dec 2020 17:37:15

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-26T09:37:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '48c42d05-7fec-4c3b-8e3b-bd3c6fdb897c' User entered 'No (N)'	System	26 Dec 2020 17:37:15
	System	26 Dec 2020 17:37:15

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-26T09:37:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '48c42d05-7fec-4c3b-8e3b-bd3c6fdb897c' User entered '26 Dec 2020 09:37:12'	System	26 Dec 2020 17:37:15
	System	26 Dec 2020 17:37:15

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-31T09:54:42', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a2b695ca-9cb0-4c40-9cb6-7480984c372f' User entered 'No (N)'	System	31 Dec 2020 17:54:56
	System	31 Dec 2020 17:54:56

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-31T09:54:49', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a2b695ca-9cb0-4c40-9cb6-7480984c372f' User entered 'No (N)'	System	31 Dec 2020 17:54:56
	System	31 Dec 2020 17:54:56

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2020-12-31T09:54:54', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a2b695ca-9cb0-4c40-9cb6-7480984c372f' User entered '31 Dec 2020 09:54:54'	System	31 Dec 2020 17:54:56
	System	31 Dec 2020 17:54:56

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-07T07:43:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '2650385a-6654-4c60-87ea-16460e0b8007' User entered 'No (N)'	System	07 Jan 2021 15:43:12
	System	07 Jan 2021 15:43:12

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-07T07:43:05', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '2650385a-6654-4c60-87ea-16460e0b8007'	System	07 Jan 2021 15:43:12
User entered 'No (N)'	System	07 Jan 2021 15:43:12

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-07T07:43:09', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '2650385a-6654-4c60-87ea-16460e0b8007' User entered '07 Jan 2021 07:43:09'	System	07 Jan 2021 15:43:12
	System	07 Jan 2021 15:43:12

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-14T07:40:01', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '51a64148-8635-4a76-bdc3-ae588274309a' User entered 'No (N)'	System	14 Jan 2021 15:40:10
	System	14 Jan 2021 15:40:10

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-14T07:40:03', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '51a64148-8635-4a76-bdc3-ae588274309a'	System	14 Jan 2021 15:40:10
User entered 'No (N)'	System	14 Jan 2021 15:40:10

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-14T07:40:08', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '51a64148-8635-4a76-bdc3-ae588274309a' User entered '14 Jan 2021 07:40:08'	System	14 Jan 2021 15:40:10
	System	14 Jan 2021 15:40:10

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-21T07:52:07', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f8f56b2e-3601-4b9b-aab7-afb4582aa4f5'	System	21 Jan 2021 15:52:17
User entered 'No (N)'	System	21 Jan 2021 15:52:17

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-21T07:52:11', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f8f56b2e-3601-4b9b-aab7-afb4582aa4f5'	System	21 Jan 2021 15:52:17
User entered 'No (N)'	System	21 Jan 2021 15:52:17

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-21T07:52:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'f8f56b2e-3601-4b9b-aab7-afb4582aa4f5' User entered '21 Jan 2021 07:52:15'	System	21 Jan 2021 15:52:17

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-28T10:49:10', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8b4a30ce-13f2-48da-8dea-5fd61e4d4dc1'	System	28 Jan 2021 18:49:19
User entered 'No (N)'	System	28 Jan 2021 18:49:19

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-28T10:49:12', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8b4a30ce-13f2-48da-8dea-5fd61e4d4dc1'	System	28 Jan 2021 18:49:19
User entered 'No (N)'	System	28 Jan 2021 18:49:19

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-01-28T10:49:15', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8b4a30ce-13f2-48da-8dea-5fd61e4d4dc1' User entered '28 Jan 2021 10:49:15'	System	28 Jan 2021 18:49:19
	System	28 Jan 2021 18:49:19

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-05T09:53:33', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf2ae886-c046-4669-aac8-91bab411cefd' User entered 'No (N)'	System	05 Feb 2021 17:53:43
	System	05 Feb 2021 17:53:43

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-05T09:53:37', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf2ae886-c046-4669-aac8-91bab411cefd' User entered 'No (N)'	System	05 Feb 2021 17:53:43

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-05T09:53:41', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cf2ae886-c046-4669-aac8-91bab411cefd' User entered '05 Feb 2021 09:53:41'	System	05 Feb 2021 17:53:43
	System	05 Feb 2021 17:53:43

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-11T07:20:31', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8712db07-c64a-440a-84a2-c5dd301a5a1f' User entered 'No (N)'	System	11 Feb 2021 15:20:41
	System	11 Feb 2021 15:20:41

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-11T07:20:34', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8712db07-c64a-440a-84a2-c5dd301a5a1f' User entered 'No (N)'	System	11 Feb 2021 15:20:41
	System	11 Feb 2021 15:20:41

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-11T07:20:38', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '8712db07-c64a-440a-84a2-c5dd301a5a1f' User entered '11 Feb 2021 07:20:38'	System	11 Feb 2021 15:20:41
	System	11 Feb 2021 15:20:41

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-19T13:14:57', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '74b78df6-2faa-4340-84e9-ea810f9ba036'	System	19 Feb 2021 21:15:15
User entered 'No (N)'	System	19 Feb 2021 21:15:15

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-19T13:15:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '74b78df6-2faa-4340-84e9-ea810f9ba036'	System	19 Feb 2021 21:15:15
User entered 'No (N)'	System	19 Feb 2021 21:15:15

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-19T13:15:13', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '74b78df6-2faa-4340-84e9-ea810f9ba036' User entered '19 Feb 2021 13:15:13'	System	19 Feb 2021 21:15:15
	System	19 Feb 2021 21:15:15

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-25T07:40:44-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4649760c-b895-4faf-8b81-ba0646b47aa5'	System	25 Feb 2021 15:40:58
User entered 'No (N)'	System	25 Feb 2021 15:40:58

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-25T07:40:48-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4649760c-b895-4faf-8b81-ba0646b47aa5'	System	25 Feb 2021 15:40:58
User entered 'No (N)'	System	25 Feb 2021 15:40:58

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-02-25T07:40:54-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '4649760c-b895-4faf-8b81-ba0646b47aa5'	System	25 Feb 2021 15:40:58
User entered '25 Feb 2021 15:40:54'	System	25 Feb 2021 15:40:58

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-06T10:53:42-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3a76ad6c-ad1b-4124-b705-d96d6d681ae6'	System	06 Mar 2021 18:53:58
User entered 'No (N)'	System	06 Mar 2021 18:53:58

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-06T10:53:44-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3a76ad6c-ad1b-4124-b705-d96d6d681ae6'	System	06 Mar 2021 18:53:58
User entered 'No (N)'	System	06 Mar 2021 18:53:58

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-06T10:53:55-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '3a76ad6c-ad1b-4124-b705-d96d6d681ae6' User entered '06 Mar 2021 10:53:55'	System	06 Mar 2021 18:53:58
	System	06 Mar 2021 18:53:58

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-12T09:43:07-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c94e7837-f795-48fb-9c16-8851feff8b77'	System	12 Mar 2021 17:43:19
User entered 'No (N)'	System	12 Mar 2021 17:43:19

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-12T09:43:11-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c94e7837-f795-48fb-9c16-8851feff8b77'	System	12 Mar 2021 17:43:19
User entered 'No (N)'	System	12 Mar 2021 17:43:19

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-12T09:43:14-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c94e7837-f795-48fb-9c16-8851feff8b77'	System	12 Mar 2021 17:43:19
User entered '12 Mar 2021 09:43:14'	System	12 Mar 2021 17:43:19

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-18T08:17:49-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cc7ce797-dff2-401a-a43c-56dbd8a66aca'	System	18 Mar 2021 15:18:03
User entered 'No (N)'	System	18 Mar 2021 15:18:03

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-18T08:17:53-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cc7ce797-dff2-401a-a43c-56dbd8a66aca'	System	18 Mar 2021 15:18:03
User entered 'No (N)'	System	18 Mar 2021 15:18:03

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-18T08:18:00-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'cc7ce797-dff2-401a-a43c-56dbd8a66aca' User entered '18 Mar 2021 08:18:00'	System	18 Mar 2021 15:18:03
	System	18 Mar 2021 15:18:03

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-25T07:59:59-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6da42e1-9523-43e2-8a66-9c46d624bbe2' User entered 'No (N)'	System	25 Mar 2021 15:00:13
	System	25 Mar 2021 15:00:13

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-25T08:00:03-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6da42e1-9523-43e2-8a66-9c46d624bbe2'	System	25 Mar 2021 15:00:13
User entered 'No (N)'	System	25 Mar 2021 15:00:13

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-25T08:00:06-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a6da42e1-9523-43e2-8a66-9c46d624bbe2' User entered '25 Mar 2021 08:00:06'	System	25 Mar 2021 15:00:13

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-01T09:16:40-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '229ee77c-8194-4711-8574-6343550bf977'	System	01 Apr 2021 16:23:47
User entered 'No (N)'	System	01 Apr 2021 16:23:47

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-01T09:16:42-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '229ee77c-8194-4711-8574-6343550bf977'	System	01 Apr 2021 16:23:47
User entered 'No (N)'	System	01 Apr 2021 16:23:47

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-01T09:16:46-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '229ee77c-8194-4711-8574-6343550bf977'	System	01 Apr 2021 16:23:47
User entered '01 Apr 2021 09:16:46'	System	01 Apr 2021 16:23:47

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-08T07:29:42-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f877428-c426-4b23-a7f6-99bf3613b8b3'	System	08 Apr 2021 14:29:52
User entered 'No (N)'	System	08 Apr 2021 14:29:52

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-08T07:29:45-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f877428-c426-4b23-a7f6-99bf3613b8b3'	System	08 Apr 2021 14:29:52
User entered 'No (N)'	System	08 Apr 2021 14:29:52

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-08T07:29:50-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '1f877428-c426-4b23-a7f6-99bf3613b8b3'	System	08 Apr 2021 14:29:52
User entered '08 Apr 2021 07:29:50'	System	08 Apr 2021 14:29:52

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-16T07:15:23-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '678bc43a-7ce6-43f2-ab4c-f1075dce8696'	System	16 Apr 2021 14:15:35
User entered 'No (N)'	System	16 Apr 2021 14:15:35

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-16T07:15:24-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '678bc43a-7ce6-43f2-ab4c-f1075dce8696'	System	16 Apr 2021 14:15:35
User entered 'No (N)'	System	16 Apr 2021 14:15:35

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-16T07:15:32-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '678bc43a-7ce6-43f2-ab4c-f1075dce8696'	System	16 Apr 2021 14:15:35
User entered '16 Apr 2021 07:15:32'	System	16 Apr 2021 14:15:35

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-23T19:52:58-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6b8671c3-32f8-427b-92ef-16ee1dd13508' User entered 'No (N)'	System	24 Apr 2021 02:53:39

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-23T19:53:03-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6b8671c3-32f8-427b-92ef-16ee1dd13508'	System	24 Apr 2021 02:53:39
User entered 'No (N)'	System	24 Apr 2021 02:53:39

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-23T19:53:08-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: '6b8671c3-32f8-427b-92ef-16ee1dd13508'	System	24 Apr 2021 02:53:39
User entered '23 Apr 2021 19:53:08'	System	24 Apr 2021 02:53:39

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-30T11:47:36-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c7233186-24ca-477e-bf54-e835953cc7d6'	System	30 Apr 2021 18:47:47
User entered 'No (N)'	System	30 Apr 2021 18:47:47

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Folder: New Safety Follow Up Diary (1)

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Have you been exposed to someone with 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 (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-30T11:47:39-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c7233186-24ca-477e-bf54-e835953cc7d6'	System	30 Apr 2021 18:47:47
User entered 'No (N)'	System	30 Apr 2021 18:47:47

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-04-30T11:47:43-07:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'c7233186-24ca-477e-bf54-e835953cc7d6'	System	30 Apr 2021 18:47:47
User entered '30 Apr 2021 11:47:43'	System	30 Apr 2021 18:47:47

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:32:40

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:32:40

US3162139

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:29:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:32:40
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:32:40

US3162139

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:29:49

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:11:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-06T10:54:21-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a62a0d83-d6f2-498d-904c-07ea9f9eda1c'	System	06 Mar 2021 18:54:44
User entered 'Yes (Y)'	System	06 Mar 2021 18:54:44

US3162139

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:29:49

Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:11:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-06T10:54:28-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a62a0d83-d6f2-498d-904c-07ea9f9eda1c'	System	06 Mar 2021 18:54:44
User entered 'No (N)'	System	06 Mar 2021 18:54:44

US3162139

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:29:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 18:11:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D048B20A-FCB7-4AB1-909E-7D898CFBA2F6)', Time: '2021-03-06T10:54:35-08:00', User OID: 'PatientReportedOutcome (US3162139)', ODM File OID: 'a62a0d83-d6f2-498d-904c-07ea9f9eda1c' User entered '06 Mar 2021 10:54:35'	System	06 Mar 2021 18:54:44
	System	06 Mar 2021 18:54:44

US3162139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 19:51:40

US3162139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '10 Nov 2020'	(b) (4), (b) (6)	11 Nov 2020 19:51:40

US3162139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	11 Nov 2020 19:51:40

US3162139

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:51:40

US3162139

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 19:51:51

US3162139

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 11:30:46
User entered 'I'	System	11 Nov 2020 19:51:51

US3162139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	16 Dec 2020 19:09:55
	(b) (4)	

US3162139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '14 Dec 2020'	Tiffany Williams (b) (4)	16 Dec 2020 19:09:55
	(b) (4)	

US3162139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	16 Dec 2020 19:09:55
	(b) (4)	

US3162139

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Dec 2020 19:09:55
	(b) (4)	

US3162139

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	16 Dec 2020 19:10:03
	(b) (4)	

US3162139

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User entered 'I'	System	16 Dec 2020 19:10:03

US3162139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	25 Jan 2021 20:40:22
	(b) (4)	

US3162139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '13 Jan 2021'	Tiffany Williams (b) (4)	25 Jan 2021 20:40:22
	(b) (4)	

US3162139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	25 Jan 2021 20:40:22
	(b) (4)	

US3162139

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	25 Jan 2021 20:40:22
	(b) (4)	

US3162139

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	25 Jan 2021 20:40:28
	(b) (4)	

US3162139

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User entered '1'	System	25 Jan 2021 20:40:28

US3162139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	16 Feb 2021 18:46:28
	(b) (4)	

US3162139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '12 Feb 2021'	Tiffany Williams (b) (4)	16 Feb 2021 18:46:28
	(b) (4)	

US3162139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	16 Feb 2021 18:46:28
	(b) (4)	

US3162139

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	16 Feb 2021 18:46:28
	(b) (4)	

US3162139

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Yes (Y)'	Tiffany Williams (b) (4)	16 Feb 2021 18:46:33
	(b) (4)	

US3162139

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 16:48:41
User entered 'I'	System	16 Feb 2021 18:46:33

US3162139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:27:35

US3162139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '23 Mar 2021'	Tiffany Williams (b) (4)	24 Mar 2021 23:27:35
	(b) (4)	

US3162139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:27:35

US3162139

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered 'VISIT4'	System	24 Mar 2021 23:27:35

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered empty.	System	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered empty.	System	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered empty.	System	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered empty.	System	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered empty.	System	30 Mar 2021 21:32:50

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41

US3162139

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41

US3162139

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	24 Mar 2021 23:27:43
	(b) (4)	

US3162139

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	24 Mar 2021 23:27:43
	(b) (4)	

US3162139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:29:20

US3162139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '23 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:29:20

US3162139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '12:30'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:29:20

US3162139

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered '23 Mar 2021 12:30'	System	24 Mar 2021 23:29:20

US3162139

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:29:27

US3162139

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:05:41
User entered 'I'	System	24 Mar 2021 23:29:27

US3162139

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 21:53:05

US3162139

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '14 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 21:53:05

US3162139

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	20 Apr 2021 21:53:05

US3162139

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 21:53:05

US3162139

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 21:53:19

US3162139

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:53:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:49:24
User closed query 'This date appears to be the date of the illness visit, not the date of when the subject made contact with the site regarding covid-like symptoms. Source indicates a call occurred on 18Oct2020 occurred with potential symptoms as well as Diary day 64 entries potentially triggering the illness visit. Please confirm the actual date in which the subject and site communicated to bring the subject in for an illness visit. Thank you!' (Site from CRA).		30 Oct 2020 23:48:22
Query 'This date appears to be the date of the illness visit, not the date of when the subject made contact with the site regarding covid-like symptoms. Source indicates a call occurred on 18Oct2020 occurred with potential symptoms as well as Diary day 64 entries potentially triggering the illness visit. Please confirm the actual date in which the subject and site communicated to bring the subject in for an illness visit. Thank you!' answered with 'Updated.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:45:05
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:44:59
User entered '18 Oct 2020' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:44:59
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:17:55

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Date of Contact](#)

Audit	User	Time (GMT)
User opened query 'This date appears to be the date of the illness visit, not the date of when the subject made contact with the site regarding covid-like symptoms. Source indicates a call occurred on 18Oct2020 occurred with potential symptoms as well as Diary day 64 entries potentially triggering the illness visit. Please confirm the actual date in which the subject and site communicated to bring the subject in for an illness visit. Thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:17:21
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:32:29

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:49:27
User closed query 'This time may need to be adjusted to account for any corrections made for "Date of Contact" on the previous query. Please confirm and update accordingly, thank you!' (Site from CRA). Query 'This time may need to be adjusted to account for any corrections made for "Date of Contact" on the previous query. Please confirm and update accordingly, thank you!' answered with 'Updated.' (Site from CRA).	(b) (4), (b) (6) Cynthia Kunakom (b) (4) (b) (4)	30 Oct 2020 23:49:21 29 Oct 2020 18:45:09
DataPoint Un-verified.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:44:59
User entered '17:41' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:44:59
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:17:55
User opened query 'This time may need to be adjusted to account for any corrections made for "Date of Contact" on the previous query. Please confirm and update accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:17:53
User entered '12:19'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:32:29

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '18 Oct 2020 17:41'	System	29 Oct 2020 18:44:59
User entered '19 Oct 2020 12:19'	System	22 Oct 2020 14:32:29

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	30 Oct 2020 23:49:29
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:05:10
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:17:55
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:32:29

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:17:55
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:32:29

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Source indicates that subject first started exhibiting various covid-like symptoms on 17Oct2020. If confirmed, then please update symptom day 1 as this date, and add all subsequent dates leading up to the illness visit. These can be marked as "Assessment Not Done". Thank you!' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 23:49:46
Query 'Source indicates that subject first started exhibiting various covid-like symptoms on 17Oct2020. If confirmed, then please update symptom day 1 as this date, and add all subsequent dates leading up to the illness visit. These can be marked as "Assessment Not Done". Thank you!' answered with 'Updated.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:39
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31
User opened query 'Source indicates that subject first started exhibiting various covid-like symptoms on 17Oct2020. If confirmed, then please update symptom day 1 as this date, and add all subsequent dates leading up to the illness visit. These can be marked as "Assessment Not Done". Thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:23:08
User entered 'Day 1 (Day 1)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '96'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '102.4' F	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'Mild (Mild)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:34:19

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Source indicates that there was an illness call 3 on 21Oct2020. Please confirm and add to EDC as necessary, thank you! Please note: source progress notes potentially refer to this as call 2 in error, as a call 2 is also recorded for 20Oct2020, source may need to be corrected as well, thank you!' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 23:50:26
Query 'Source indicates that there was an illness call 3 on 21Oct2020. Please confirm and add to EDC as necessary, thank you! Please note: source progress notes potentially refer to this as call 2 in error, as a call 2 is also recorded for 20Oct2020, source may need to be corrected as well, thank you!' answered with 'Updated.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:56
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31
User opened query 'Source indicates that there was an illness call 3 on 21Oct2020. Please confirm and add to EDC as necessary, thank you! Please note: source progress notes potentially refer to this as call 2 in error, as a call 2 is also recorded for 20Oct2020, source may need to be corrected as well, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:27:26
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '20 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '97'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:18:01
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:51:56
User entered '98.1' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:51:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered '36.7' F	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'Mild (Mild)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:16
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:49:59

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 1 (Day 1)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '17 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:15:42
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User closed query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).		15 Feb 2021 21:27:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
Query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' answered with 'updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 22:59:05
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 22:58:40
User opened query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:14:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Jan 2021 22:58:40
User entered empty.	System	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '102.4' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:44:54
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:15:42
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:15:42
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:47:03
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:11

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '18 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:44:54
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	0 Apr 2021 14:32:03
User closed query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).		5 Feb 2021 21:27:43
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
Query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' answered with 'updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 22:59:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 22:58:40
User opened query 'Per CDM: It appears that O2 Saturation is missing. If not collected, please consider recording this as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:15:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Jan 2021 22:58:40
User entered empty.	System	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '101.0' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Mild (Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:50:24
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:54:31

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:16:38
User entered 'Day 3 (Day 3)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '21 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '97'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '97.8' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 18:53:39
User entered '36.6' C	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Mild (Mild)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

US3162139

Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 17:55:28

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 09:30:31
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Updated.' (Site from DM).	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:55:39
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 09:05:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:51:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:51:07
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:51:07
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:40:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 15:32:58
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 15:32:58
User entered '19 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Oct 2020 15:32:58
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:40:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:51:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:51:07
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:51:07
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:40:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:51:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:51:07
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:51:07
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:40:38
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

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[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:33
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:40:38

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Folder: Covid-19 Assessment 18 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '0'	System	22 Oct 2020 14:51:07

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Folder: Covid-19 Assessment 18 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:29:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:24:50
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:32:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:16:46
User entered '25 Aug 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:16:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:24
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:13:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:16:46
User entered '08:27' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:16:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:24
User entered '16:41'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:13:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '25 Aug 2020 08:27'	System	29 Oct 2020 19:16:46
User entered '26 Aug 2020 16:41'	System	28 Aug 2020 21:13:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:16:46
User entered 'Safety Call (Safety Call)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:16:46
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:24
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:13:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:29:49

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:01:24
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:13:45

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Source progress notes indicate patient had symptoms of nausea on 22Aug2020. Please confirm, and add all subsequent dates leading up to illness visit as "Assessment Not Done" if needed, thank you!' (Site from CRA).	(b) (4), (b) (6)	30 Oct 2020 23:52:59
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:32:24
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:57
Query 'Source progress notes indicate patient had symptoms of nausea on 22Aug2020. Please confirm, and add all subsequent dates leading up to illness visit as "Assessment Not Done" if needed, thank you!' answered with 'Updated.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:59
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:58
User opened query 'Source progress notes indicate patient had symptoms of nausea on 22Aug2020. Please confirm, and add all subsequent dates leading up to illness visit as "Assessment Not Done" if needed, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:03:41
User entered 'Day 1 (Day 1)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per CDM: it appears Contact date was 25AUG2020 yet date of initial symptoms is recorded as Day 5 with date of 26AUG2020. Please reconcile and confirm this is the actual initial date of symptoms or update accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 03:28:13
Query 'Per CDM: it appears Contact date was 25AUG2020 yet date of initial symptoms is recorded as Day 5 with date of 26AUG2020. Please reconcile and confirm this is the actual initial date of symptoms or update accordingly.' answered with 'correct as written' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	04 Nov 2020 15:39:45
User opened query 'Per CDM: it appears Contact date was 25AUG2020 yet date of initial symptoms is recorded as Day 5 with date of 26AUG2020. Please reconcile and confirm this is the actual initial date of symptoms or update accordingly.' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 12:13:41
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '98'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '99.1' F	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:03

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:32:24
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:57
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:30:07
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '27 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '95'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '97.6' F	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'Moderate (Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:17:54

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:32:24
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:57
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:30:17
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:51
User entered 'Day 4 (Day 4)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '28 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '99'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '97.8' F	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:45:49
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:45:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'Not Done (Not Done)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'Mild (Mild)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:34:40

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:32:24
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:57
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:30:27
User entered 'Day 4 (Day 4)'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '29 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '97' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	01 Sep 2020 19:07:06
User entered empty.	System	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:46:57
User entered '97.3' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:46:57
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '36.3' C reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:06
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:36:46

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:32:24
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:29:47
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:30:36
User entered 'Day 5 (Day 5)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '30 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '98'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '97.7' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:48:49
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:47:51
User entered '97.7' C reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:47:51
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '36.5' C	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:07:49

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:32:24
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:29:47
User entered 'Day 10 (Day 10)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:30:44
User entered 'Day 6 (Day 6)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '31 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '98'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:48:49
User entered '97.7' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:48:49
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered '36.5' C	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:05
User entered 'None (None)'	Cynthia Kunakom (b) (4) (b) (4)	03 Sep 2020 16:54:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'Day 1 (Day 1)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered '22 Aug 2020'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered '1'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

O2 Saturation

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User closed query 'Per CDM: It appears that O2 Saturation and temperature are missing for Day 1-4. If not collected, please consider recording these as Not Done.' (Site from DM).		15 Feb 2021 21:28:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
Query 'Per CDM: It appears that O2 Saturation and temperature are missing for Day 1-4. If not collected, please consider recording these as Not Done.' answered with 'Updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:29
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User opened query 'Per CDM: It appears that O2 Saturation and temperature are missing for Day 1-4. If not collected, please consider recording these as Not Done.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 18:17:06
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered empty.	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Jan 2021 23:01:12
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4)	29 Oct 2020 19:30:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4)	29 Oct 2020 19:27:41
	(b) (4)	
User entered empty.	System	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

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[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered empty.	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Form: Symptom Log (7)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'Mild (Mild)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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Form: Symptom Log (7)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint activated with code reason code Data required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:30:50
DataPoint inactivated with code reason code Data not required.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:27:41
User entered 'None (None)'	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:29:11

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[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:31:16
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:04
User entered 'Day 2 (Day 2)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Form: Symptom Log (8)

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[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '23 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Jan 2021 23:01:12
User entered empty.	System	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Form: Symptom Log (8)

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[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:40:15
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:50:56

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:31:16
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:04
User entered 'Day 3 (Day 3)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '24 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Jan 2021 23:01:12
User entered empty.	System	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:42:05
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:06

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:31:16
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:28:04
User entered 'Day 4 (Day 4)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

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Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '%'	System	31 Jan 2021 23:01:12
User entered empty.	System	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered missing code ND - Not Done; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	31 Jan 2021 23:01:12
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 15:29:49

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'None (None)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:43:52
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:51:44

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:59:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 20:59:12
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 20:59:12
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 21:15:58
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

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Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:10:18
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:15:58

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 15:29:49

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User entered '0'	System	14 Sep 2020 20:59:12

US3162139

Folder: Covid-19 Assessment 25 Aug 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:29:49

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 14:32:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
Query 'This needs to be marked "No" unless subject exhibited onset of new covid symptoms separate from this initial instance. Please confirm and update accordingly, thank you!' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:12:03
	(b) (4), (b) (6)	27 Oct 2020 21:11:17
User opened query 'This needs to be marked "No" unless subject exhibited onset of new covid symptoms separate from this initial instance. Please confirm and update accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:10:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:31:37
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	22 Sep 2020 15:44:53

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User closed query 'Per source, a second illness visit occurred on 19Oct2020. A new "Saliva Collection (2)" page has not been created or completed for this visit. Please update EDC accordingly with this information, thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 23:37:15
Query 'Per source, a second illness visit occurred on 19Oct2020. A new "Saliva Collection (2)" page has not been created or completed for this visit. Please update EDC accordingly with this information, thank you!' answered with 'Updated.' (Site from CRA).	Cynthia Kunakom (b) (4)	29 Oct 2020 18:56:10
User opened query 'Per source, a second illness visit occurred on 19Oct2020. A new "Saliva Collection (2)" page has not been created or completed for this visit. Please update EDC accordingly with this information, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:38:18
User accepted default value 'Day 3 (Day 3)'	Cynthia Kunakom (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '28 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 5 (Day 5)'	Cynthia Kunakom (b) (4)	01 Sep 2020 19:09:21
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:47:13
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:47:15
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 06:27:57
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with ' 1F607VT is the accession number for Day 5 saliva. The date of collection is wrong on the report. It says 28Aug, and should say 30Aug. ' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	22 Dec 2020 02:14:05
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 30AUG2020 is recorded under Illness Visit Day 5 in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 07:06:34

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 07:06:22
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.'	Cynthia Kunakom (b) (4)	29 Oct 2020 18:56:48
' answered with 'Sample was received on 22OCT and collected on 21OCT. This is now in saliva log for illness visit 2.' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 22OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.'	(b) (4), (b) (6)	29 Oct 2020 11:05:21
(Site from DM).		
User closed query 'Per GCL Lab Recon: GCL is reporting receiving saliva sample for 01Sep2020 and in not reporting receiving a saliva sample for 30Aug2020. Please clarify these dates.' (Site from DM).		29 Oct 2020 11:04:47
Query 'Per GCL Lab Recon: GCL is reporting receiving saliva sample for 01Sep2020 and in not reporting receiving a saliva sample for 30Aug2020. Please clarify these dates.'	Judith Kirstein (b) (4)	26 Oct 2020 05:13:19
answered with 'Saliva was collected on 30Aug2020' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Recon: GCL is reporting receiving saliva sample for 01Sep2020 and in not reporting receiving a saliva sample for 30Aug2020. Please clarify these dates.' (Site from DM).	(b) (4), (b) (6)	25 Oct 2020 21:16:17
User entered '30 Aug 2020'	Cynthia Kunakom (b) (4)	01 Sep 2020 19:09:21
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM). Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'Subject did not have a saliva on 01Sep and I do not see one listed for that date in PPD Central lab.' (Site from DM).	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	20 Nov 2020 10:55:47 06 Nov 2020 01:02:50
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 01SEP2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. '(Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:50:44
User accepted default value 'Day 7 (Day 7)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:49

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'If saliva was not collected because subject nasal swab came back negative, then the answer for this and all subsequent log lines will need to be "NA - Covid19 Negative". Please confirm and update EDC accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 23:37:51
Query 'If saliva was not collected because subject nasal swab came back negative, then the answer for this and all subsequent log lines will need to be "NA - Covid19 Negative". Please confirm and update EDC accordingly, thank you!' answered with 'Will be fixed' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:41:06
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:40:50
User opened query 'If saliva was not collected because subject nasal swab came back negative, then the answer for this and all subsequent log lines will need to be "NA - Covid19 Negative". Please confirm and update EDC accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:32:35
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:02:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 21:02:03
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 21:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:09:21
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 9 (Day 9)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:41:19
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:02:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 21:02:03
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 21:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:09:21
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 14 (Day 14)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:41:27
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:02:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 21:02:03
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 21:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:09:21
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 21 (Day 21)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:49

Was Saliva Collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:41:35
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:02:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 21:02:03
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 21:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:09:21
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 28 (Day 28)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	28 Oct 2020 20:41:42
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 21:02:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 21:02:03
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 21:02:03
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Sep 2020 19:09:21
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:21

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 3 (Day 3)'	Cynthia Kunakom (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '21 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 5 (Day 5)'	Cynthia Kunakom (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 7 (Day 7)'	Cynthia Kunakom (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 9 (Day 9)'	Cynthia Kunakom (b) (4)	29 Oct 2020 18:04:46
	(b) (4)	

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 14 (Day 14)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 21 (Day 21)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:49

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User accepted default value 'Day 28 (Day 28)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'NA (COVID-19 Negative) (NA)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:04:46

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per source, a second illness visit occurred on 19Oct2020. The "Covid-19 Assessment" page has been completed for this visit, but the "Illness Visit Day 1 (2)" page has not been created or completed for this visit. Please add this information into EDC, thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 23:38:17
Query 'Per source, a second illness visit occurred on 19Oct2020. The "Covid-19 Assessment" page has been completed for this visit, but the "Illness Visit Day 1 (2)" page has not been created or completed for this visit. Please add this information into EDC, thank you!' answered with 'This is updated.' (Site from CRA).	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:57:15
User opened query 'Per source, a second illness visit occurred on 19Oct2020. The "Covid-19 Assessment" page has been completed for this visit, but the "Illness Visit Day 1 (2)" page has not been created or completed for this visit. Please add this information into EDC, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 21:36:37
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:28:26
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:43

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:28:26
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:43

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:28:26
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:09:43

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'SICKD1'	System	01 Sep 2020 19:09:43

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '16:55'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered '26 Aug 2020 16:55'	System	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '162.6' cm	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36
DataPoint set to visible.	System	01 Sep 2020 19:09:43

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '71.7' kg	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36
DataPoint set to visible.	System	01 Sep 2020 19:09:43

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '37.3' C	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '82'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'bpm'	System	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '14'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'breaths/min'	System	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '149'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'mmHg'	System	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:20
User entered '86'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'mmHg'	System	01 Sep 2020 19:10:36

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19

US3162139

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:27
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:48

US3162139

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:27
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:10:48

US3162139

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:29:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:37
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:11:00

US3162139

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:29:37
User entered '26 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	01 Sep 2020 19:11:00

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:15:52
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:14:42

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:15:52
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:14:42

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:15:52
User entered 'Clinic (Clinic)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:14:42

US3162139

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'SICKD1'	System	29 Oct 2020 18:14:42

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '11:48'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered '19 Oct 2020 11:48'	System	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '162.6' cm	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29
DataPoint set to visible.	System	29 Oct 2020 18:14:42

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '71' kg	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29
DataPoint set to visible.	System	29 Oct 2020 18:14:42

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '38.5' C	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered 'Oral (Oral)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '94'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'bpm'	System	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '13'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'breaths/min'	System	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '150'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'mmHg'	System	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:43
User entered '78'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User entered 'mmHg'	System	29 Oct 2020 18:15:29

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19

US3162139

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19

US3162139

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:53
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:37

US3162139

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:16:53
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:37

US3162139

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:29:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:17:01
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:44

US3162139

Folder: Illness Visit Day 1 (1)

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

Generated On: 09 Jun 2021 15:29:49

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:41:19
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	04 Feb 2021 01:17:01
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	29 Oct 2020 18:15:44

US3162139

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

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:20

US3162139

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

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:20

US3162139

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

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:20

US3162139

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

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 21:49:20

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:39:09

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(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 05:39:09

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Placebo (Placebo)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '1'	System	25 Jan 2021 21:49:39

US3162139

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

Form: Unblinding

Generated On: 09 Jun 2021 15:29:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'I'	System	25 Jan 2021 21:49:39

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '64' in	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '156' lb	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '26.83333'	System	29 Jan 2021 18:05:49
DataPoint set to visible.	System	25 Jan 2021 21:49:39

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '64' in	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '156' lb	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '26.83333'	System	29 Jan 2021 18:05:49
DataPoint set to visible.	System	25 Jan 2021 21:49:39

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4)	29 Jan 2021 18:05:49
	(b) (4)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '25 Jan 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '10:48' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '25 Jan 2021 10:48'	System	21 Feb 2021 06:17:48
User entered empty.	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '98.5' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered 'Oral (Oral)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '73' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'bpm'	System	21 Feb 2021 06:17:48
User entered empty.	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '13' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'breaths/min'	System	21 Feb 2021 06:17:48
User entered empty.	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '141' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	21 Feb 2021 06:17:48
User entered empty.	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '77' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	21 Feb 2021 06:17:48
User entered empty.	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '64' in	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '156' lb	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:29:49

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '26.83333'	System	29 Jan 2021 18:05:49
DataPoint set to visible.	System	25 Jan 2021 21:49:39

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '13:29' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '10:48'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '25 Jan 2021 13:29'	System	21 Feb 2021 06:17:48
User entered '25 Jan 2021 10:48'	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '98.6' F reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '98.5' F	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '73'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'bpm'	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '13'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'breaths/min'	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '140' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '141'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User entered '96' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	21 Feb 2021 06:17:48
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '77'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:05:49

US3162139

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	29 Jan 2021 18:05:49

US3162139

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:08

US3162139

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:08

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mRNA-1273'	System	25 Jan 2021 21:50:21
DataPoint set to visible.	System	25 Jan 2021 21:49:39

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '12:54'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '25 Jan 2021 12:54'	System	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4) (b) (4)	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'ONCE'	System	25 Jan 2021 21:50:21

US3162139

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

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 21:50:21

US3162139

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:34

US3162139

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:34

US3162139

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '11:08'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:34

US3162139

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '25 Jan 2021 11:08'	System	29 Jan 2021 18:06:34

US3162139

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:55

US3162139

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '25 Jan 2021'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:55

US3162139

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '11:02'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:06:55

US3162139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:29:49

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '25 Jan 2021 11:02'	System	29 Jan 2021 18:06:55

US3162139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	29 Jan 2021 18:07:01

US3162139

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'I'	System	29 Jan 2021 18:07:01

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 23:31:59

US3162139

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered '1 Feb 2021'	Tiffany Williams (b) (4)	02 Feb 2021 23:31:59
	(b) (4)	

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Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 23:31:59

US3162139

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:19:38
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	02 Feb 2021 23:31:59
	(b) (4)	

US3162139

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:19:38
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Feb 2021 23:32:04

US3162139

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'I'	System	02 Feb 2021 23:32:04

US3162139

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'I'	System	02 Feb 2021 23:32:04
DataPoint set to visible.	System	02 Feb 2021 23:32:04

US3162139

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:26:05

US3162139

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '22 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:26:05

US3162139

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	22 Feb 2021 22:26:05
	(b) (4)	

US3162139

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'OLD29'	System	22 Feb 2021 22:26:05

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User accepted default value 'Pre-Dose (PREDOSE)'	Tiffany Williams (b) (4)	22 Feb 2021 22:28:49
	(b) (4)	

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '22 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '11:38'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '22 Feb 2021 11:38'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '97.3' F	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '52'	Tiffany Williams (b) (4)	22 Feb 2021 22:28:49
	(b) (4)	

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'bpm'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '12'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'breaths/min'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '108'	Tiffany Williams (b) (4)	22 Feb 2021 22:28:49
	(b) (4)	

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User closed query 'Per CDM: Kindly clarify whether Diastolic BP is CS or NCS. If CS, consider adding an AE.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 03:20:46
Query 'Per CDM: Kindly clarify whether Diastolic BP is CS or NCS. If CS, consider adding an AE.' answered with 'NCS' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	07 Mar 2021 07:44:29
User opened query 'Per CDM: Kindly clarify whether Diastolic BP is CS or NCS. If CS, consider adding an AE.' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 09:38:50
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Mar 2021 09:38:10
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'PER SOURCE' (Site from System).	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:29:12
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		22 Feb 2021 22:28:49
User entered '59'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User accepted default value 'Post-Dose (POSTDOSE)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '22 Feb 2021'	Tiffany Williams (b) (4)	22 Feb 2021 22:28:49
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '13:00'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '22 Feb 2021 13:00'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '98.4' F	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Oral (Oral)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '55'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'bpm'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '13'	Tiffany Williams (b) (4)	22 Feb 2021 22:28:49
	(b) (4)	

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Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'breaths/min'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '120'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '61'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mmHg'	System	22 Feb 2021 22:28:49

US3162139

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'No (N)'	Tiffany Williams (b) (4)	22 Feb 2021 22:29:55
	(b) (4)	

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Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:29:55

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:30:16

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	22 Feb 2021 22:30:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

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)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	22 Feb 2021 22:30:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'mRNA-1273'	System	22 Feb 2021 22:30:16
DataPoint set to visible.	System	02 Feb 2021 23:32:04

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '22 Feb 2021'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:30:16

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '12:25'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:30:16

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '22 Feb 2021 12:25'	System	22 Feb 2021 22:30:16

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Tiffany Williams (b) (4)	22 Feb 2021 22:30:16
	(b) (4)	

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Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'ONCE'	System	22 Feb 2021 22:30:16

US3162139

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:29:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'INTRAMUSCULAR'	System	22 Feb 2021 22:30:16

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	22 Feb 2021 22:30:23

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Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'I'	System	22 Feb 2021 22:30:23

US3162139

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Mar 2021 17:49:37

US3162139

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '1 Mar 2021'	Tiffany Williams (b) (4)	02 Mar 2021 17:49:37
	(b) (4)	

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Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Tiffany Williams (b) (4)	02 Mar 2021 17:49:37
	(b) (4)	

US3162139

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:29:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	02 Mar 2021 17:49:37

US3162139

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	02 Mar 2021 17:49:42

US3162139

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:29:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'I'	System	02 Mar 2021 17:49:42

US3162139

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:30:40

US3162139

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '23 Mar 2021'	Tiffany Williams (b) (4)	24 Mar 2021 23:30:40
	(b) (4)	

US3162139

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Clinic (Clinic)'	Tiffany Williams (b) (4)	24 Mar 2021 23:30:40
	(b) (4)	

US3162139

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:29:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered 'OLD57'	System	24 Mar 2021 23:30:40

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered empty.	System	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered empty.	System	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered empty.	System	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered empty.	System	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered empty.	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:23

US3162139

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered empty.	System	24 Mar 2021 23:32:23

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31

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Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:29:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31

US3162139

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'No (N)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:34

US3162139

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:29:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	Tiffany Williams (b) (4)	24 Mar 2021 23:32:34
	(b) (4)	

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'Yes (Y)'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:51

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '23 Mar 2021'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:51

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '12:30'	Tiffany Williams (b) (4) (b) (4)	24 Mar 2021 23:32:51

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Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:29:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:33:31
User entered '23 Mar 2021 12:30'	System	24 Mar 2021 23:32:51

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:29:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:38:43
User entered 'Yes (Y)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:10:59
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:53:06

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:46:29
Query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' answered with 'Yes, and swab was negative' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 20:18:47
User opened query 'Per MM: Please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 12:37:56
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:10:42
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:13:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 21:13:41
Data point term sent to Coder	System	28 Aug 2020 21:13:08
User entered 'Nausea'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 20:54:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 20:54:29
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 20:54:29
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 21:12:22
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

US3162139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 23 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 17:27:07
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 23 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' answered with 'Corrected date' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:17:27
User entered '23 Aug 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:17:17
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 23 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 14:17:29
User closed query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 23 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates.' (Site from DM).		19 Nov 2020 13:20:46
User entered '22 Aug 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:33:48
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:18:44
User entered '23 Aug 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:18:44
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59

US3162139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 23 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' answered with 'A solicited reaction does not become an AE until day 8. Please get familiar with the Solicited AR guidelines.' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	29 Sep 2020 04:34:39
User opened query 'Per DM CLR: Please note that this AE start date does not match the Diary initial start date of Solicited Symptom NAUSEA on 23 AUG 2020. Please review if this should be reconciled. Else, provide clarification on dates. ' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 01:38:02
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		17 Sep 2020 00:12:52
User opened query 'Adverse Event Start Date is before treatment date at Visit 2. Please review and reconcile. (per protocol any adverse event prior to first dose should be recorded as Medical History).' (Site from System).	System	15 Sep 2020 21:01:12
User entered '25 Aug 2020'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User entered empty.	System	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'No (N)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:32:44
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '29 Aug 2020' reason for change: New Information	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:26:54
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:25:40
User entered '28 Aug 2020' reason for change: New Information	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:25:40
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '29 Aug 2020' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:32:44
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Sep 2020 20:09:53
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 20:09:53
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	15 Sep 2020 20:09:32
User entered '07:00' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	15 Sep 2020 20:09:32
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User entered empty.	System	15 Sep 2020 20:09:53
User entered '29 Aug 2020 07:00'	System	15 Sep 2020 20:09:32
User entered empty.	System	28 Aug 2020 21:12:22

US3162139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:37:20
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	29 Oct 2020 19:37:20
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

US3162139

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'None (NONE)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'I'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Cynthia Kunakom (b) (4) (b) (4)	31 Aug 2020 15:32:44
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User entered '0'	System	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49
User entered 'I'	System	28 Aug 2020 21:12:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per MM: This subject presented with fever, muscle aches, fatigue, headaches (onsets 17Oct2020) - please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 03:46:40
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Procedural related injuries and complications NEC, HLT: Vaccination related complications, PT: Vaccination complication, LLT: Vaccination complication - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:29:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 03:29:50
Data point term sent to Coder	System	17 Nov 2020 01:56:31
User closed query 'For coding purposes, please specify the type of REACTION TO SHINGRIX VACCINE' (Site from System).	System	17 Nov 2020 01:55:38
Query 'For coding purposes, please specify the type of REACTION TO SHINGRIX VACCINE' answered with 'CORRECTED' (Site from System).	Judith Kirstein (b) (4) (b) (4)	17 Nov 2020 01:55:38
Data point term sent to Coder	System	17 Nov 2020 01:55:30
User entered 'FEBRILE REACTION TO SHINGRIX VACCINE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	17 Nov 2020 01:55:21
User opened query 'For coding purposes, please specify the type of REACTION TO SHINGRIX VACCINE' (Site from System).	Coder Import (b) (4) (b) (4)	17 Nov 2020 01:50:58
Query 'Per MM: This subject presented with fever, muscle aches, fatigue, headaches (onsets 17Oct2020) - please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' answered with 'Yes, and swab was negative. AE term has now been changed to "Reaction to Shingrix vaccine" and other symptoms have been deleted, as they were all part of the reaction' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	14 Nov 2020 20:20:37
Data point term sent to Coder	System	14 Nov 2020 20:20:00

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Judith Kirstein (b) (4)	14 Nov 2020 20:19:37
	(b) (4)	
Coding entries removed.	Judith Kirstein (b) (4)	14 Nov 2020 20:19:37
	(b) (4)	
User entered 'REACTION TO SHINGRIX VACCINE' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 20:19:37
	(b) (4)	
User opened query 'Per MM: This subject presented with fever, muscle aches, fatigue, headaches (onsets 17Oct2020) - please confirm if this is a symptom of COVID and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 12:39:28
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:00:33
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 16:00:33
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 15:59:41
Coding entries removed.	Judith Kirstein (b) (4)	22 Oct 2020 15:59:33
	(b) (4)	
User entered 'FATIGUE' reason for change: Data Entry Error	Judith Kirstein (b) (4)	22 Oct 2020 15:59:33
	(b) (4)	
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:24:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 19:24:43
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:23:54
User entered 'headaches'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:23:45
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Oct 2020 14:52:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Oct 2020 14:52:26
User entered 'No (N)' reason for change: Data Entry Error	Cynthia Kunakom (b) (4) (b) (4)	22 Oct 2020 14:52:26
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:23:45
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '17 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Oct 2020 15:59:33
User entered '18 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User entered empty.	System	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '22 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Oct 2020 15:59:33
User entered '19 Oct 2020'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User entered empty.	System	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Oct 2020 15:59:33
User entered 'Grade 1/Mild (Grade 1/Mild)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'No (N)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Not Related (NOT RELATED)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'None (NONE)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User closed query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#12 & 13) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 19:58:58
Query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#12 & 13) recorded that matches this AE during this timeframe. Please review and update this field.' answered with 'Corrected' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:18:37
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:18:26
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:18:26
User opened query 'Per DM CLR: Other Action Taken = None, however there are Concomitant Medications (#12 & 13) recorded that matches this AE during this timeframe. Please review and update this field.' (Site from DM).	(b) (4), (b) (6)	21 Nov 2020 14:18:15
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Oct 2020 15:59:33
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:18:26
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Nov 2020 22:18:26
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Oct 2020 15:59:33
User entered '1'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered '0'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:39:59
User entered empty.	Cynthia Kunakom (b) (4) (b) (4)	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User entered '0'	System	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54
User entered 'I'	System	21 Oct 2020 19:23:45

US3162139

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:30:54

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'USA-US074-2021-mRNA-1273-P301000013'	System	23 Feb 2021 15:52:56
User entered 'New'	(b) (4), (b) (6)	23 Feb 2021 15:52:56

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension worsened - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:45:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Feb 2021 20:45:03
Data point term sent to Coder	System	22 Feb 2021 20:29:43
User entered 'worsening of hypertension'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:50:21
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
User entered '16 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Feb 2021 20:29:08
User entered empty; reason for change Data Entry Error	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:29:08
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	22 Feb 2021 20:28:43
User entered '16:00'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 20:29:08
User entered '17 Feb 2021 16:00'	System	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Thank you for your response, but it does not match the eSource AE Log, Please Verify. Thank you' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4)	12 Apr 2021 21:50:16
User signature succeeded.	(b) (4), (b) (6) (b) (4)	12 Apr 2021 21:50:13
Query 'Thank you for your response, but it does not match the eSource AE Log, Please Verify. Thank you' answered with 'Source updated' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:21:30
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Apr 2021 04:25:42
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 04:25:22
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	03 Apr 2021 04:25:22
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 04:24:54
User entered 'Yes (Y)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 04:24:54
User opened query 'Thank you for your response, but it does not match the eSource AE Log, Please Verify. Thank you' (Site from CRA).	(b) (4), (b) (6) (b) (4)	03 Apr 2021 01:04:37
User closed query 'Please review the subject's BP on 22 Feb 2021 during the OL-D29 visit. Verify if this AE can have a resolution date based on those vital signs. Thank you.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	03 Apr 2021 01:04:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
Query 'Please review the subject's BP on 22 Feb 2021 during the OL-D29 visit. Verify if this AE can have a resolution date based on those vital signs. Thank you.' answered with 'It resolved by 17FEB21' (Site from CRA).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:27:19
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (6)

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[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
User opened query 'Please review the subject's BP on 22 Feb 2021 during the OL-D29 visit. Verify if this AE can have a resolution date based on those vital signs. Thank you.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Mar 2021 17:49:50 02 Mar 2021 22:37:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:50:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 15:46:26
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Provided' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:27:31
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
User entered '17 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:01:51
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'Grade 4 (Grade 4)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:50:59
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
User entered '16 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:51:05
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 15:46:37
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'Hospital records will be sent very soon' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 20:43:00
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
User entered '17 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:02:44
User entered '18 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:50:53
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User closed query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 25 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 15:46:49
Query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 25 Jan 2021, then event occurred).' answered with 'Second OL dose given on time' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:28:58
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	07 Mar 2021 07:43:30
User entered 'None (NONE)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	07 Mar 2021 07:43:30
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User opened query 'PV Query: Please update action taken to reflect the action taken with mRNA-1273 (unblinded and received first dose on 25 Jan 2021, then event occurred).' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:00:56
User entered 'Not Applicable (NOT APPLICABLE)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:50:45
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	24 Mar 2021 15:46:57
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'Resolved' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:29:13
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 16:01:34
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:37:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 21:50:47
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User closed query 'Per DM CLR: Narrative = WORKUP THE NEXT MORNING, INCLUDING STRESS TEST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:43:21
User closed query 'PV Query: Please provide the results of stress test' (Site from Safety).		24 Mar 2021 15:47:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include (stress test) units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).		24 Mar 2021 15:47:25
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).		24 Mar 2021 15:47:15
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include (stress test) units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' answered with 'Results of all tests are being sent' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 20:43:26

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS HYPERTENSION, AND ON 16FEB2021, HER SYSTOLIC BP WAS 185 ON HOME UNIT. KAISER NURSE ADVISED HER TO GO TO ER AND THERE, IT WAS 183. SHE WAS ADMITTED OVERNIGHT SO SHE COULD HAVE WORKUP THE NEXT MORNING, INCLUDING STRESS TEST. AFTER THE WORKUP, SHE WAS DISCHARGED. HYDROCHLOROTHIAZIDE WAS STOPPED AND LISINOPRIL AND METOPROLOL WERE STARTED AND BY 17FEB21, HER BP WAS CONTROLLED.' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 20:38:08
Query 'Per DM CLR: Narrative = WORKUP THE NEXT MORNING, INCLUDING STRESS TEST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'All diagnostic procedures have been entered in the Con Proc eCRF and EDC' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 20:36:53
Query 'PV Query: Please provide the results of stress test' answered with 'Per report: No significant electrocardiogram changes with Lexiscan infusion. No arrhythmia observed beyond base line.' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 20:35:55
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' answered with 'Nasal/throat swab (not NP swab) was done on 16FEB21 and was negative.' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:30:08
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:26:48

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT HAS HYPERTENSION, AND ON 16FEB2021, HER SYSTOLIC BP WAS 185 ON HOME UNIT. KAISER NURSE ADVISED HER TO GO TO ER AND THERE, IT WAS ALSO 185. SHE WAS ADMITTED OVERNIGHT SO SHE COULD HAVE WORKUP THE NEXT MORNING, INCLUDING STRESS TEST. AFTER THE WORKUP, SHE WAS DISCHARGED. HYDROCHLOROTHIAZIDE WAS STOPPED AND LISINOPRIL AND METOPROLOL WERE STARTED and by 17FEB21, her BP was well controlled.' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 05:26:48
User opened query 'Per DM CLR: Narrative = WORKUP THE NEXT MORNING, INCLUDING STRESS TEST. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 06:59:51
User opened query 'PV Query: Please provide the results of stress test' (Site from Safety).		12 Mar 2021 16:55:40
DataPoint Verified.		02 Mar 2021 22:37:35
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include (stress test) units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response' (Site from Safety).		02 Mar 2021 16:01:20
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so. [mRNA-1273 protocols where subject was hospitalization during study participation]' (Site from Safety).		02 Mar 2021 16:01:08

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject has hypertension, and on 17FEB2021, her systolic BP was 185 on home unit. Kaiser nurse advised her to go to ER and there, it was also 185. She was admitted overnight so she could have workup the next morning, including stress test. After the workup, she was discharged. Hydrochlorothiazide was stopped and Lisinopril and Metoprolol were started.'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 20:28:43

US3162139

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 20:28:43

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:35
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'USA-US074-2021-mRNA-1273-P301000013'	(b) (4), (b) (6)	24 Mar 2021 15:45:54

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:50
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:32:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Mar 2021 08:32:30
Data point term sent to Coder	System	23 Mar 2021 06:07:16
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:06:38
User entered 'worsening of ATYPICAL CHEST PAIN' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:06:38
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Unspecified chest pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 05:44:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 05:44:35
Data point term sent to Coder	System	23 Mar 2021 05:44:10
User entered 'atypical chest pain'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:54
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:55
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:13:57
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:00
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '1 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:02
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:04
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:06
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:07
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

Severity

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 22:46:26
User closed query 'Per source, severity is recorded as 'grade 4'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 22:46:13
Query 'Per source, severity is recorded as 'grade 4'. Please reconcile. ' answered with 'data entry error. updated per eSource' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:26:03
Signature has been broken.	(b) (4), (b) (6)	16 Apr 2021 19:23:33
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 19:23:33
User opened query 'Per source, severity is recorded as 'grade 4'. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:13:27
Query 'Per source, the severity grading is recorded as 'grade 4'. Please reconcile. ' canceled (Site from CRA).		16 Apr 2021 19:11:56
User opened query 'Per source, the severity grading is recorded as 'grade 4'. Please reconcile. ' (Site from CRA).		16 Apr 2021 19:11:33
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:21:30
User closed query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 11:26:49
Query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' answered with 'Updated' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 05:07:06
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 05:06:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 05:06:49

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Folder: Adverse Events

Form: Adverse Events (7)

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[Severity](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: AE Grade = 1, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1. Please review and update the grade or provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4)	03 Apr 2021 04:51:30
	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:12
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:14
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:16
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

US3162139

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:18
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered 'I'	Judith Kirstein (b) (4)	23 Mar 2021 05:43:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:25
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '16 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

US3162139

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:30
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:36
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:14:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:18:41
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:21:30
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 05:10:24
User entered '1' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 05:10:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:31
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	23 Mar 2021 05:43:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:37
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

US3162139

Folder: Adverse Events

Form: Adverse Events (7)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:40
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'None (NONE)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:43
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 05:43:29
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:15:46
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

US3162139

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:16:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

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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)	16 Apr 2021 19:16:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

US3162139

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:18
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:21:30
User closed query 'PV Query: Please provide the date, units of measure and reference ranges for the potassium. ' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 14:44:01
Query 'PV Query: Please provide the date, units of measure and reference ranges for the potassium. ' answered with 'Added to narrative' (Site from Safety).	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 04:33:12
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 04:32:53
User entered 'SUBJECT WENT TO ER ON 16FEB21 BECAUSE HER BP WAS ELEVATED, BUT ER PHYSICIAN ELICITED A HISTORY OF ATYPICAL CHEST PAIN THAT HAD BEEN OCCURRING SINCE 2001, BUT HAD WORSENERD AROUND 01FEB21. ON THE BASIS OF THIS, THE SUBJECT WAS ADMITTED TO RULE OUT MYOCARDIAL DISEASE. THIS WAS THE ACTUAL SAE, NOT THE ELEVATED BP, BUT IT WAS CLARIFIED ONLY AFTER SUBJECT HOSPITAL RECORDS WERE RECEIVED. SUBJECT'S TROPONIN WAS SLIGHTLY ELEVATED (.06, WITH NORMAL BEING <.03 NG/ML). THIS DECREASED TO .05. HER ECG WAS NORMAL. MYOCARDIAL PERFUSION SCAN WAS NORMAL. STRESS TEST WITH NUCLEAR IMAGING WAS NORMAL. TRANSTHORACIC ECHO SHOWED NORMAL EJECTION FRACTION AND WALL MOTION. SUBJECT HAD HYPOKALEMIA on 16FEB21,(POTASSIUM 3.3 meq/liter, with normal range being 3.5-5 meq/liter) WHICH CORRECTED TO 3.6 AFTER A KCL BOLUS. HER ATORVASTATIN WAS INCREASED TO 40 MG AND ASPIRIN 81 MG DAILY WAS STARTED. SHE WAS DISCHARGED HOME ON 17FEB21' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	03 Apr 2021 04:32:53

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (7)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the date, units of measure and reference ranges for the potassium. ' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) [REDACTED] Judith Kirstein (b) (4) [REDACTED] (b) (4) [REDACTED]	02 Apr 2021 16:25:30 29 Mar 2021 06:59:35
User entered 'SUBJECT WENT TO ER ON 16FEB21 BECAUSE HER BP WAS ELEVATED, BUT ER PHYSICIAN ELICITED A HISTORY OF ATYPICAL CHEST PAIN THAT HAD BEEN OCCURRING since 2001, BUT HAD WORSENERED AROUND 01FEB21. ON THE BASIS OF THIS, THE SUBJECT WAS ADMITTED TO RULE OUT MYOCARDIAL DISEASE. THIS WAS THE ACTUAL SAE, NOT THE ELEVATED BP, BUT IT WAS CLARIFIED ONLY AFTER SUBJECT HOSPITAL RECORDS WERE RECEIVED. SUBJECT'S TROPONIN WAS SLIGHTLY ELEVATED (.06, WITH NORMAL BEING <.03 NG/ML). THIS DECREASED TO .05. HER ECG WAS NORMAL. MYOCARDIAL PERFUSION SCAN WAS NORMAL. STRESS TEST WITH NUCLEAR IMAGING WAS NORMAL. TRANSTHORACIC ECHO SHOWED NORMAL EJECTION FRACTION AND WALL MOTION. SUBJECT HAD HYPOKALEMIA (POTASSIUM 3.3) WHICH CORRECTED TO 3.6 AFTER A KCL BOLUS. HER ATORVASTATIN WAS INCREASED TO 40 MG AND ASPIRIN 81 MG DAILY WAS STARTED. SHE WAS DISCHARGED HOME ON 17FEB21' reason for change: Data Entry Error	Judith Kirstein (b) (4) [REDACTED] (b) (4) [REDACTED]	23 Mar 2021 17:00:11

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WENT TO ER ON 16FEB21 BECAUSE HER BP WAS ELEVATED, BUT ER PHYSICIAN ELICITED A HISTORY OF ATYPICAL CHEST PAIN THAT HAD BEEN OCCURRING FOR YEARS, BUT HAD WORSENERD AROUND 01FEB21. ON THE BASIS OF THIS, THE SUBJECT WAS ADMITTED TO RULE OUT MYOCARDIAL DISEASE. THIS WAS THE ACTUAL SAE, NOT THE ELEVATED BP, BUT IT WAS CLARIFIED ONLY AFTER SUBJECT HOSPITAL RECORDS WERE RECEIVED. SUBJECT'S TROPONIN WAS SLIGHTLY ELEVATED (.06, WITH NORMAL BEING <.03 NG/ML). THIS DECREASED TO .05. HER ECG WAS NORMAL. MYOCARDIAL PERFUSION SCAN WAS NORMAL. STRESS TEST WITH NUCLEAR IMAGING WAS NORMAL. TRANSTHORACIC ECHO SHOWED NORMAL EJECTION FRACTION AND WALL MOTION. SUBJECT HAD HYPOKALEMIA (POTASSIUM 3.3) WHICH CORRECTED TO 3.6 AFTER A KCL BOLUS. HER ATORVASTATIN WAS INCREASED TO 40 MG AND ASPIRIN 81 MG DAILY WAS STARTED. She was discharged home on 17FEB21' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:45:02

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject went to ER on 16FEB21 because her BP was elevated, but ER physician elicited a history of atypical chest pain that had been occurring for years, but had worsened around 01FEB21. On the basis of this, the subject was admitted to rule out myocardial disease. This was the actual SAE, not the elevated BP, but it was clarified only after subject hospital records were received. Subject's troponin was slightly elevated (.06, with normal being <.03 ng/ml). This decreased to .05. Her ECG was normal. Myocardial perfusion scan was normal. Stress test with nuclear imaging was normal. Transthoracic ECHO showed normal ejection fraction and wall motion. Subject had hypokalemia (Potassium 3.3) which corrected to 3.6 after a KCl bolus. Her atorvastatin was increased to 40 mg and Aspirin 81 mg daily was started.'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Mar 2021 05:43:29

US3162139

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Mar 2021 05:43:29

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Potassium imbalance, PT: Hypokalaemia, LLT: Hypokalemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:14:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:14:31
Data point term sent to Coder	System	23 Mar 2021 06:13:18
User entered 'hypokalemia'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '16 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User entered empty.	System	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '17 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 16:42:16
User entered '16 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User entered empty.	System	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

US3162139

Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered 'None (NONE)'	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

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Generated On: 09 Jun 2021 15:29:49

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered 'I'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4)	29 Mar 2021 06:59:35
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Judith Kirstein (b) (4)	23 Mar 2021 06:13:05
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

US3162139

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	29 Mar 2021 06:59:35
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 06:13:05

US3162139

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User entered '0'	System	23 Mar 2021 06:13:05

US3162139

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03
User entered 'I'	System	23 Mar 2021 06:13:05

US3162139

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 15:29:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:31:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:29:49

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:28
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).		30 Mar 2021 10:46:37
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' answered with 'con med log updated, per query request.' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 21:04:49
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:29:01
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 21:42:48
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:53:32

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 04:55:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 04:55:12
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 04:54:36
User entered 'hydrochlorothiazide'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'hypertension'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 20:59:42
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '25'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once daily (QD)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	24 Mar 2021 21:00:55
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:54:01
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:51
DataPoint Un-verified.	Judith Kirstein (b) (4)	22 Feb 2021 20:46:16
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	22 Feb 2021 20:46:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	22 Feb 2021 20:46:16
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 05:49:25
	(b) (4)	
User entered '16 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 05:49:25
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:53
DataPoint Un-verified.	Judith Kirstein (b) (4)	22 Feb 2021 20:46:16
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	22 Feb 2021 20:46:16
	(b) (4)	
User entered '17 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	22 Feb 2021 20:46:16
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 04:54:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Aug 2020 04:54:08
User entered 'No (N)' reason for change: Data Entry Error	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Aug 2020 04:54:01
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User entered '1'	System	19 Aug 2020 04:54:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User entered '1'	System	19 Aug 2020 04:54:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:23
User entered '804 (804)'	System	19 Aug 2020 04:54:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:11:42
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 21:11:42
Data point term sent to Coder	System	22 Sep 2020 21:10:44
User entered 'Tylenol'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'chronic right knee pain'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '500'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'UN UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Sep 2020 21:09:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	19 Aug 2020 04:56:13
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Aug 2020 04:56:13
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	19 Aug 2020 04:55:36
User entered 'atorvastatin'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'hyperlipidemia'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '20'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'other (OTHER)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'three times per week'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:54:55
User entered 'un UNK 2019'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 06:11:00
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	23 Mar 2021 06:11:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:11:00
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 06:11:00
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	23 Mar 2021 06:11:00
	(b) (4)	
User entered '15 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:11:00
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User entered empty.	System	19 Aug 2020 04:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User entered empty.	System	19 Aug 2020 04:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:06:38
User entered empty.	System	19 Aug 2020 04:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 12:46:12
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 12:46:12
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 04:56:37
User entered 'estradiol vaginal ring'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be removed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 13:44:24
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be removed as appropriate. Otherwise, provide clarification.' answered with 'corrected' (Site from DM).	Judith Kirstein (b) (4)	04 Oct 2020 04:26:21
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	04 Oct 2020 04:26:09
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be removed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 12:53:37
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'atrophic vaginitis'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '7.5'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User closed query 'Per DM CLR: Please review and correct UNIT, as this is not an expected unit of dose for this medication. Review if this should be mcg/h. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 17:18:14
Query 'Per DM CLR: Please review and correct UNIT, as this is not an expected unit of dose for this medication. Review if this should be mcg/h. Update as appropriate. ' answered with 'Unit corrected' (Site from DM).	Judith Kirstein (b) (4)	14 Sep 2020 20:58:39
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 20:58:28
User opened query 'Per DM CLR: Please review and correct UNIT, as this is not an expected unit of dose for this medication. Review if this should be mcg/h. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 11:33:44
User entered 'mg (mg)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'other (OTHER)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'continuous'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Vaginal (VAGINAL)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:55:51
User entered 'un UNK 2010'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 17:20:40
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	23 Mar 2021 17:20:40
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 17:20:40
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 17:20:40
	(b) (4)	
Signature has been broken.	Judith Kirstein (b) (4)	23 Mar 2021 17:20:40
	(b) (4)	
User entered '21 Jan 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 17:20:40
	(b) (4)	
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4)	19 Aug 2020 04:55:51
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User entered empty.	System	19 Aug 2020 04:55:51

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User entered empty.	System	19 Aug 2020 04:55:51

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:07:12
User entered empty.	System	19 Aug 2020 04:55:51

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 05:51:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 05:51:31
Data point term sent to Coder DataPoint Un-verified.	System Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:50:11 23 Mar 2021 05:49:51
Coding entries removed.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:49:51
Signature has been broken.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:49:51
User entered 'FAMOTIDINE' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:49:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:43:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:43:22

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Aug 2020 04:56:37
User entered 'famotidine'	Jared Bradshaw (b) (4)	19 Aug 2020 04:56:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'acid reflux'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '40'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:56:15
User entered 'un UNK 2010'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 04:56:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:59:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:59:13
Data point term sent to Coder	System	19 Aug 2020 04:57:37
User entered 'alprazolam'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'anxiety'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0.5'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'as needed (PRN)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:56:58
User entered 'un UNK 2015'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 04:56:58

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:59:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:59:13
Data point term sent to Coder	System	19 Aug 2020 04:57:37
User entered 'vitamin b12'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '2500'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Other (OTHER)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mcg'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:57:34
User entered 'un UNK 2019'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 04:57:34

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
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;VITAMIN D NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:31:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 06:31:18
Data point term sent to Coder	System	19 Aug 2020 04:58:38
User entered 'calcium/vit d'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '1200/1000'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Other (OTHER)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg/iu'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:58:16
User entered 'un UNK 2010'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 04:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
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.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:59:13
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 04:59:13
Data point term sent to Coder	System	19 Aug 2020 04:58:38
User entered 'multivitamin'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:58:36
User entered 'un UNK 2010'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 04:58:36

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: VARIOUS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, ATC: ALL OTHER NON-THERAPEUTIC PRODUCTS, PRODUCT: HYALURONIC ACID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 05:01:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 05:01:15
Data point term sent to Coder	System	19 Aug 2020 04:59:38
User entered 'hyaluronic acid'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User closed query 'Per MM: Please revise the indication.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 16:28:08
Query 'Per MM: Please revise the indication.' answered with 'Correct as written' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	14 Sep 2020 21:00:39
User opened query 'Per MM: Please revise the indication.' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 17:56:04
User entered 'nutritional supplement'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'I'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'tablet (TABLET)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once daily (QD)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:24:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 04:59:07
User entered 'un UNK 2019'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 04:59:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User closed query 'Per Hospital Records Page 3, the subject received a second Shingles Vaccination on 05 Jan 2021, please verify and update eSource and EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 19:00:44
Query 'Per Hospital Records Page 3, the subject received a second Shingles Vaccination on 05 Jan 2021, please verify and update eSource and EDC accordingly. Thank you.' answered with 'con med log updated in eSource and EDC, per query request ' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 23:51:14
User opened query 'Per Hospital Records Page 3, the subject received a second Shingles Vaccination on 05 Jan 2021, please verify and update eSource and EDC accordingly. Thank you.' (Site from CRA).	(b) (4), (b) (6)	15 Apr 2021 22:03:01
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 19:19:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	21 Oct 2020 19:19:35
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:18:45
User entered 'Shingrix'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Shingles prevention'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0.5'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mL (mL)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'once (ONCE)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Intramuscular (INTRAMUSCULAR)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '16 Oct 2020'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '16 Oct 2020'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:18:21
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User entered empty.	System	21 Oct 2020 19:18:21

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User entered empty.	System	21 Oct 2020 19:18:21

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:25
User entered empty.	System	21 Oct 2020 19:18:21

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
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.	Coder Import (b) (4)	14 Nov 2020 21:10:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 21:10:52
	(b) (4)	
Data point term sent to Coder	System	14 Nov 2020 21:10:11
Coding entries removed.	Judith Kirstein (b) (4)	14 Nov 2020 21:09:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
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.	Coder Import (b) (4)	21 Oct 2020 19:20:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:20:43
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:19:46
User entered 'Acetaminophen'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:34:34
DataPoint Un-verified.	Judith Kirstein (b) (4)	14 Nov 2020 21:09:15
	(b) (4)	
User entered 'REACTION TO SHINGRIX VACCINE' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 21:09:15
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'fever'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '1000'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '17 Oct 2020'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:34:30
User closed query 'Per source, subject discontinued medication on 19Oct2020, please confirm and update accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 23:34:27
Query 'Per source, subject discontinued medication on 19Oct2020, please confirm and update accordingly, thank you!' answered with 'updated' (Site from CRA).	Judith Kirstein (b) (4)	29 Oct 2020 16:27:39
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	29 Oct 2020 16:27:30
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	29 Oct 2020 16:27:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User opened query 'Per source, subject discontinued medication on 19Oct2020, please confirm and update accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:03:42
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	29 Oct 2020 16:27:30
	(b) (4)	
User entered '19 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	29 Oct 2020 16:27:30
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:11
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User entered empty.	System	21 Oct 2020 19:19:11

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User entered empty.	System	21 Oct 2020 19:19:11

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:36
User entered empty.	System	21 Oct 2020 19:19:11

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
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.	Coder Import (b) (4)	14 Nov 2020 21:10:52
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 21:10:52
	(b) (4)	
Data point term sent to Coder	System	14 Nov 2020 21:10:12
Coding entries removed.	Judith Kirstein (b) (4)	14 Nov 2020 21:09:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
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.	Coder Import (b) (4)	21 Oct 2020 19:21:14
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:21:14
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:19:47
User entered 'Acetaminophen'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:35:11
DataPoint Un-verified.	Judith Kirstein (b) (4)	14 Nov 2020 21:09:43
	(b) (4)	
User entered 'REACTION TO SHINGRIX VACCINE' reason for change: Data Entry Error	Judith Kirstein (b) (4)	14 Nov 2020 21:09:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'muscle aches and headaches'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '500'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'mg (mg)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'as needed (PRN)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'Oral (ORAL)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '18 Oct 2020'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered '0'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:35:05
User closed query 'Per source, subject discontinued medication on 20Oct2020, please confirm and update accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	23 Nov 2020 23:35:00
Query 'Per source, subject discontinued medication on 20Oct2020, please confirm and update accordingly, thank you!' answered with 'changed' (Site from CRA).	Judith Kirstein (b) (4)	29 Oct 2020 16:29:35
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	29 Oct 2020 16:29:27
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	29 Oct 2020 16:29:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User opened query 'Per source, subject discontinued medication on 20Oct2020, please confirm and update accordingly, thank you!' (Site from CRA).	(b) (4), (b) (6)	27 Oct 2020 22:04:28
User entered 'Yes (Y)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 23:35:08
DataPoint Un-verified.	Judith Kirstein (b) (4)	29 Oct 2020 16:29:27
	(b) (4)	
User entered '20 Oct 2020' reason for change: Data Entry Error	Judith Kirstein (b) (4)	29 Oct 2020 16:29:27
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered empty.	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:36
User entered 'No (N)'	Cynthia Kunakom (b) (4)	21 Oct 2020 19:19:37
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User entered empty.	System	21 Oct 2020 19:19:37

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User entered empty.	System	21 Oct 2020 19:19:37

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:48
User entered empty.	System	21 Oct 2020 19:19:37

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 19:55:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Nov 2020 19:55:35
	(b) (4)	
Data point term sent to Coder	System	11 Nov 2020 19:55:05
User entered 'Influenza vaccine'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Influenza prevention'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '0.5'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '16 Oct 2020'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User entered empty.	System	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User entered empty.	System	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:57
User entered empty.	System	11 Nov 2020 19:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 21:51:06
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 Feb 2021 21:51:06
Data point term sent to Coder	System	22 Feb 2021 21:49:41
User entered 'lisinopril'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'worsening of hypertension'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered '5'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Un-verified.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:50:19
User entered '16 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:50:19
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered '0'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 21:49:01

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:08:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Feb 2021 07:08:08
	(b) (4)	
Data point term sent to Coder	System	22 Feb 2021 21:50:42
User entered 'metoprolol tartrate'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'worsening of hypertension'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered '12.5'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'mg (mg)'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered empty.	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'twice daily (BID)'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered empty.	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered empty.	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 05:51:08
	(b) (4)	
User entered '16 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 05:51:08
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered '0'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 17:03:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 17:03:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Un-verified.	Judith Kirstein (b) (4)	23 Mar 2021 17:03:17
	(b) (4)	
User entered '19 Mar 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 17:03:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered empty.	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 22:38:28
User entered 'No (N)'	Judith Kirstein (b) (4)	22 Feb 2021 21:50:23
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User entered '2'	System	22 Feb 2021 21:50:23

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User entered '1'	System	22 Feb 2021 21:50:23

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:05:13
User entered '804 (804)'	System	22 Feb 2021 21:50:23

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:50:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 19:50:43
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 19:50:20
Data point term sent to Coder	System	23 Mar 2021 05:53:12
User entered 'Potassium chloride'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Hypokalemia'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '40'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Other (OTHER)'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'meq'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 19:49:31
	(b) (4)	
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 05:53:05
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User entered empty.	System	23 Mar 2021 05:53:05

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User entered empty.	System	23 Mar 2021 05:53:05

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:16
User entered empty.	System	23 Mar 2021 05:53:05

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:29:21
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Mar 2021 14:29:21
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 05:55:12
User entered 'Heparin'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Yes (Y)'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Prevent thrombotic event'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '5000'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'IU (IU)'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'twice daily (BID)'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 05:54:55
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User entered '2'	System	23 Mar 2021 05:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User entered '1'	System	23 Mar 2021 05:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:24
User entered '804 (804)'	System	23 Mar 2021 05:54:55

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 05:57:31
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 05:57:31
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 05:56:13
User entered 'atorvastatin'	Judith Kirstein (b) (4)	23 Mar 2021 05:56:07
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'hyperlipidemia'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '20' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:01:00
User entered '40'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '18 Feb 2021' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:01:00
User entered '16 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 05:56:07

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 20:52:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Mar 2021 20:52:40
Data point term sent to Coder	System	24 Mar 2021 20:52:27
Coding entries removed.	(b) (4), (b) (6)	24 Mar 2021 20:51:49
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:00:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 06:00:38
Data point term sent to Coder	System	23 Mar 2021 05:59:14
User entered 'aspirin'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'CARDIAC PROTECTION' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:51:49
User entered 'cardiac prophylaxis'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '81'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 22:07:51
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 05:58:16

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: REGADENOSON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:25:25
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 10:25:25
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 06:08:16
Data point term sent to Coder	System	23 Mar 2021 06:01:14
User entered 'regadenoson (contrast agent for myocardial perfusion scan)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'worsening of ATYPICAL CHEST PAIN' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:07:19
	(b) (4)	
User entered 'atypical chest pain'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0.4'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'mg (mg)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:00:26
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User entered empty.	System	23 Mar 2021 06:00:26

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User entered empty.	System	23 Mar 2021 06:00:26

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:02
User entered empty.	System	23 Mar 2021 06:00:26

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: HOMEOPATHIC PREPARATION, PRODUCT: THALLIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 12:36:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 12:36:40
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 06:09:18
Data point term sent to Coder	System	23 Mar 2021 06:02:15
User entered 'Thallium (Agent for stress test with nuclear imaging)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'WORSENING OF ATYPICAL CHEST PAIN' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:08:20
	(b) (4)	
User entered 'Atypical chest pain'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '3.6'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Other (OTHER)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'millicurie' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:08:20
	(b) (4)	
User entered 'mCi'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:02:03
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User entered empty.	System	23 Mar 2021 06:02:03

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User entered empty.	System	23 Mar 2021 06:02:03

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:13
User entered empty.	System	23 Mar 2021 06:02:03

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: VARIOUS, ATC: DIAGNOSTIC RADIOPHARMACEUTICALS, ATC: CARDIOVASCULAR SYSTEM, ATC: TECHNETIUM (99MTC) COMPOUNDS, PRODUCT: TECHNETIUM (99M TC) SESTAMIBI - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 11:05:26
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 11:05:26
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 06:09:17
Data point term sent to Coder	System	23 Mar 2021 06:04:15
User entered 'TC sestamibi (AGENT FOR STRESS TEST WITH NUCLEAR IMAGING)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'WORSENING OF ATYPICAL CHEST PAIN' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:09:02
	(b) (4)	
User entered 'atypical chest pain'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '26.9'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Other (OTHER)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Millicurie' reason for change: Data Entry Error	Judith Kirstein (b) (4)	23 Mar 2021 06:09:02
	(b) (4)	
User entered 'mCi'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 06:03:43
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User entered empty.	System	23 Mar 2021 06:03:43

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User entered empty.	System	23 Mar 2021 06:03:43

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:30
User entered empty.	System	23 Mar 2021 06:03:43

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 17:03:38
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	23 Mar 2021 17:03:38
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	23 Mar 2021 17:02:44
User entered 'atorvastatin'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'hyperlipidemia'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '40'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'mg (mg)'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once daily (QD)'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 17:02:15
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User entered '1'	System	23 Mar 2021 17:02:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User entered '1'	System	23 Mar 2021 17:02:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:56
User entered '804 (804)'	System	23 Mar 2021 17:02:15

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 20 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:13:40
Query 'Per DM CLR: this Con Med was added/ had dose increased on 20 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'Subject had been started on BID dosing in the hospital, due to worsening of hypertension, but once it was controlled, she dropped down to once per day on 20MAR2021 for hypertension ' (Site from DM).	Judith Kirstein (b) (4) (b) (4)	05 Apr 2021 20:27:51
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 20 MAR 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:24:12
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 17:05:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Mar 2021 17:05:39
Data point term sent to Coder	System	23 Mar 2021 17:04:48

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'metoprolol tartrate'	Judith Kirstein (b) (4)	23 Mar 2021 17:04:38
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'hypertension'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '12.5'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'mg (mg)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'once daily (QD)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '20 Mar 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 17:04:38

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User closed query 'Per DM CLR: this Con Med was added/ had dose increased on 8 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM). Query 'Per DM CLR: this Con Med was added/ had dose increased on 8 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'She switched from using the ring to using cream. There was no worsening.' (Site from DM).	(b) (4), (b) (6) Judith Kirstein (b) (4) (b) (4)	06 Apr 2021 13:13:47 05 Apr 2021 20:22:40
User opened query 'Per DM CLR: this Con Med was added/ had dose increased on 8 FEB 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:25:28
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:06
Data point term sent to Coder	System	23 Mar 2021 17:23:18
User entered 'estradiol .01% vaginal cream'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'atrophic vaginitis'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User closed query 'Per DM CLR: Note, 1 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate.' (Site from DM). Query 'Per DM CLR: Note, 1 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate.' answered with '1 is not a concentration. She is using 1 gram. See dose unit.' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:13:52
User opened query 'Per DM CLR: Note, 1 is a concentration, please update medication name to include this concentration and update dose and dose unit with the actual dose administered (eg, 1000ml, 500ml, etc). Update as appropriate.' (Site from DM). User entered '1'	Judith Kirstein (b) (4) (b) (4)	05 Apr 2021 20:23:29
	(b) (4), (b) (6)	05 Apr 2021 04:25:35
	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'g (g)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'every week (QS)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Vaginal (VAGINAL)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '8 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	23 Mar 2021 17:22:47

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, MODERATELY POTENT (GROUP II), PRODUCT: TRIAMCINOLONE ACETONIDE, PRODUCTSYNONYM: KENALOG [TRIAMCINOLONE ACETONIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:38:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	07 Apr 2021 15:38:45
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 17:32:32
User entered 'Kenalog in Orabase (0.1% Triamcinolone paste)'	Judith Kirstein (b) (4)	23 Mar 2021 17:31:40
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Intermittent aphthous stomatitis'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '1'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Other (OTHER)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'application'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'as needed (PRN)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Topical (TOPICAL)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'UN UNK 2001'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '0'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Mar 2021 17:31:40

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 20:37:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 20:37:41
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 20:36:45
Coding entries removed.	(b) (4), (b) (6)	24 Mar 2021 20:36:05
User entered 'Tylenol' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:36:05
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.	Coder Import (b) (4)	23 Mar 2021 17:44:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 17:44:39
	(b) (4)	
Data point term sent to Coder	System	23 Mar 2021 17:44:06
User entered 'Acetaminophen'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	06 Apr 2021 13:14:01
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' answered with 'Med was given in the ER, but no reason was stated, and she did not remember having any problem that necessitated Tylenol, did not even remember taking it.' (Site from DM).	Judith Kirstein (b) (4)	05 Apr 2021 20:21:18
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate. (if indication is a mechanism of Action, Drug class, etc.) ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 04:26:00
User entered 'Unknown'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '650'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'mg (mg)'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once (ONCE)'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Oral (ORAL)'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Judith Kirstein (b) (4)	23 Mar 2021 17:43:30
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User entered empty.	System	23 Mar 2021 17:43:30

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User entered empty.	System	23 Mar 2021 17:43:30

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:04:47
User entered empty.	System	23 Mar 2021 17:43:30

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 20:42:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 20:42:42
	(b) (4)	
Data point term sent to Coder	System	24 Mar 2021 20:42:12
User entered 'Aspirin' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
Data point term sent to Coder	System	24 Mar 2021 20:37:51
User entered 'THALLIUM (AGENT FOR STRESS TEST WITH NUCLEAR IMAGING)' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:37:47
Data point term sent to Coder	System	24 Mar 2021 02:19:30
User entered 'REGADENOSON (CONTRAST AGENT FOR MYOCARDIAL PERFUSION SCAN)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered 'No (N)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Cardiac Prophylaxis' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered 'worsening of atypical chest pain'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '325' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered '3.6'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'mg (mg)' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered 'Other (OTHER)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty; reason for change New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered 'millicuries'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'once (ONCE)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'Oral (ORAL)' reason for change: New Information	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered 'Intravenous (INTRAVENOUS)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered empty.	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered '17 Feb 2021'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '0'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered '16 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Mar 2021 20:42:09
User entered '17 Feb 2021'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:25:24
	(b) (4)	
User entered 'No (N)'	Jessica Fisher (b) (4)	24 Mar 2021 02:19:24
	(b) (4)	

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User entered empty.	System	24 Mar 2021 02:19:24

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User entered empty.	System	24 Mar 2021 02:19:24

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:03:04
User entered empty.	System	24 Mar 2021 02:19:24

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: HYALURONIC ACID, PRODUCTSYNONYM: RESTYLANE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:39:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Mar 2021 10:39:25
Data point term sent to Coder	System	24 Mar 2021 21:04:51
User entered 'Restylane'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Cosmetic- Upper lip'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'UNKNOWN'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Other (OTHER)'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Vial'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'as needed (PRN)'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'UN UNK 1996'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered '0'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered empty.	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:25:24
User entered 'No (N)'	(b) (4), (b) (6)	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 21:03:59

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE RGE (CHO), PRODUCTSYNONYM: SHINGRIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 23:51:08
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Apr 2021 23:51:08
	(b) (4)	
Data point term sent to Coder	System	15 Apr 2021 23:49:53
User entered 'Shingrix'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Prevent Shingles'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '0.5'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '05 Jan 2021'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered '05 Jan 2021'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User signature succeeded.	Judith Kirstein (b) (4)	24 Apr 2021 23:07:15
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User entered empty.	System	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User entered empty.	System	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 15:29:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:02:54
User entered empty.	System	15 Apr 2021 23:49:49

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:29:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:03:28
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
DataPoint Un-verified.	Jessica Fisher (b) (4) (b) (4)	14 Jan 2021 05:18:06
User entered 'Yes (Y)' reason for change: New Information	Jessica Fisher (b) (4) (b) (4)	14 Jan 2021 05:18:06
DataPoint Verified.	(b) (4), (b) (6)	27 Oct 2020 22:04:49
User entered 'No (N)'	Jared Bradshaw (b) (4) (b) (4)	19 Aug 2020 04:53:12

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered '05 Jan 2021'	Jessica Fisher (b) (4) (b) (4)	14 Jan 2021 05:18:33

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'right knee xray'	Jessica Fisher (b) (4) (b) (4)	14 Jan 2021 05:18:33

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Medical History (MH)'	Jessica Fisher (b) (4) (b) (4)	14 Jan 2021 05:18:33

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Jessica Fisher (b) (4) (b) (4)	14 Jan 2021 05:18:33

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:22
User signature succeeded.	Judith Kirstein (b) (4)	15 Feb 2021 04:05:10
	(b) (4)	
User entered '21 Jan 2021'	Jessica Fisher (b) (4)	28 Jan 2021 21:59:48
	(b) (4)	

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Right breast biopsy'	Jessica Fisher (b) (4) (b) (4)	28 Jan 2021 21:59:48

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered 'Diagnostic (DIAGNOSTIC)'	Jessica Fisher (b) (4) (b) (4)	28 Jan 2021 21:59:48

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:22
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	15 Feb 2021 04:05:10
User entered empty.	Jessica Fisher (b) (4) (b) (4)	28 Jan 2021 21:59:48

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:24
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:46:07
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'myocardial perfusion scan'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:46:07

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:50:32
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:46:07

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:24
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:46:07

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:26
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered '17 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:47:01
	(b) (4)	

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'transthoracic echocardiogram'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:47:01

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:26
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:50:44
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:47:01

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:26
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 05:47:01
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered '17 Feb 2021'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:47:50

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'Cardiac stress test with nuclear imaging'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:47:50

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:50:54
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:47:50

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:29
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:47:50

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 05:48:47
	(b) (4)	

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:32
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered 'Electrocardiogram'	Judith Kirstein (b) (4)	23 Mar 2021 05:48:47
	(b) (4)	

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Data Entry Error	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 17:51:06
User entered 'Adverse Event (AE)'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:48:47

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:32
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered empty.	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 05:48:47

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:34
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered '16 Feb 2021'	Judith Kirstein (b) (4)	23 Mar 2021 20:08:16
	(b) (4)	

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:34
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	08 Apr 2021 21:29:48
User entered 'Chest Xray'	Judith Kirstein (b) (4) (b) (4)	23 Mar 2021 20:08:16

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:34
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered 'Diagnostic (DIAGNOSTIC)'	Judith Kirstein (b) (4)	23 Mar 2021 20:08:16
	(b) (4)	

US3162139

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 15:29:49

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:27:34
User signature succeeded.	Judith Kirstein (b) (4)	08 Apr 2021 21:29:48
	(b) (4)	
User entered empty.	Judith Kirstein (b) (4)	23 Mar 2021 20:08:16
	(b) (4)	

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'USA-US074-2021-MRNA-1273-P301000013'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
Un-reviewed for Safety.	System	03 Apr 2021 05:10:24
User entered 'Yes (Y)'	System	03 Apr 2021 05:10:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Judith'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Kirstein'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'BANNING'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'CA'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '92220'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'US'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Apr 2021 15:54:47
User entered '4'	System	05 Apr 2021 13:11:25
User entered '3'	System	24 Mar 2021 15:49:21
User entered '2'	System	08 Mar 2021 16:37:54
User entered '1'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'USA-US074-2021-MRNA-1273-P301000013'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Serious](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
Un-reviewed for Safety.	System	03 Apr 2021 05:10:24
User entered 'Yes (Y)'	System	03 Apr 2021 05:10:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Judith'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Kirstein'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'BANNING'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'CA'		23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '92220'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'US'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Apr 2021 15:54:47
User entered '4'	System	05 Apr 2021 13:11:25
User entered '3'	System	24 Mar 2021 15:49:21
User entered '2'	System	08 Mar 2021 16:37:54
User entered '1'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
User entered '23/Feb/2021 10:57'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:29:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'I'		23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'USA-US074-2021-MRNA-1273-P301000013'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
Un-reviewed for Safety.	System	03 Apr 2021 05:10:24
User entered 'Yes (Y)'	System	03 Apr 2021 05:10:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Judith'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Kirstein'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'BANNING'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'CA'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '92220'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'US'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Apr 2021 15:54:47
User entered '4'	System	05 Apr 2021 13:11:25
User entered '3'	System	24 Mar 2021 15:49:21
User entered '2'	System	08 Mar 2021 16:37:54
User entered '1'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
User entered '08/Mar/2021 11:37'	System	08 Mar 2021 16:37:54

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:29:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		24 Mar 2021 15:49:02
User entered 'I'		08 Mar 2021 16:37:54

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'USA-US074-2021-MRNA-1273-P301000013'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
Un-reviewed for Safety.	System	03 Apr 2021 05:10:24
User entered 'Yes (Y)'	System	03 Apr 2021 05:10:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Judith'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Kirstein'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'BANNING'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'CA'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '92220'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'US'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Apr 2021 15:54:47
User entered '4'	System	05 Apr 2021 13:11:25
User entered '3'	System	24 Mar 2021 15:49:21
User entered '2'	System	08 Mar 2021 16:37:54
User entered '1'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
User entered '24/Mar/2021 11:49'	System	24 Mar 2021 15:49:21

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:29:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
User entered 'I'		24 Mar 2021 15:49:21

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'USA-US074-2021-MRNA-1273-P301000013'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
Un-reviewed for Safety.	System	03 Apr 2021 05:10:24
User entered 'Yes (Y)'	System	03 Apr 2021 05:10:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Judith'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Kirstein'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'BANNING'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'CA'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '92220'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'US'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Apr 2021 15:54:47
User entered '4'	System	05 Apr 2021 13:11:25
User entered '3'	System	24 Mar 2021 15:49:21
User entered '2'	System	08 Mar 2021 16:37:54
User entered '1'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
User entered '05/Apr/2021 06:11'	System	05 Apr 2021 13:11:25

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:29:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
User entered 'I'		05 Apr 2021 13:11:25

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'USA-US074-2021-MRNA-1273-P301000013'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Yes (Y)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 15:54:30
DataPoint Verified.		16 Apr 2021 19:20:53
Un-reviewed for Safety.	System	03 Apr 2021 05:10:24
User entered 'Yes (Y)'	System	03 Apr 2021 05:10:24
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 15:57:33
User entered 'No (N)'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Judith'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

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[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'Kirstein'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '264 N HIGHLAND SPRINGS AVE, SUITE 4'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'BANNING'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'CA'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered '92220'	System	23 Feb 2021 15:52:56

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 19:20:53
Reviewed for Safety.		23 Feb 2021 15:57:33
User entered 'US'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form

Generated On: 09 Jun 2021 15:29:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	19 Apr 2021 15:54:47
User entered '4'	System	05 Apr 2021 13:11:25
User entered '3'	System	24 Mar 2021 15:49:21
User entered '2'	System	08 Mar 2021 16:37:54
User entered '1'	System	23 Feb 2021 15:57:29

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:29:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered '19/Apr/2021 11:54'	System	19 Apr 2021 15:54:47

US3162139

Folder: SAE USA-US074-2021-MRNA-1273-P301000013

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:29:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Judith Kirstein (b) (4) (b) (4)	24 Apr 2021 23:07:15
User entered 'I'	(b) (4), (b) (6)	19 Apr 2021 15:54:47