

US3492107 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:59:21

All time stamps listed in this document are displayed in GMT

US3492107

Form: Participant Creation

Data signed: (b) (4) 15 Feb 2021 03:43:01

Generated On: 10 Jun 2021 07:59:21

[Participant ID](#)

US3492107

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

US3492107

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 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	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	75
Age Units	YEARS
Age (Derived)	75
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 15 Feb 2021 03:43:11

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Date of Informed Consent (<i>dd MMM yyyy</i>)	9 SEP 2020
Month and Year of Informed Consent (derived)	SEP 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 03:43:11

Generated On: 10 Jun 2021 07:59:21

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 03:43:11

Generated On: 10 Jun 2021 07:59:21

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	CAROTID ARTERY DISEASE
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 (2)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	OSTEOARTHRITIS OF RIGHT KNEE, RIGHT HIP, LUMBAR SPINE
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	TYPE 1 DIABETES
Start date (dd MMM yyyy)	UN UNK 1970
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 1970
Start Year (derived)	1970
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	ANXIETY
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) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	POST-MENOPAUSAL
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	HYPERTENSION
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	FACIAL HAIR
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	SPINAL STENOSIS
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	LUMBAR SPINAL FUSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Condition	DETACHED RETINA
Start date (dd MMM yyyy)	
Start date completely unknown	True
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)	
Start Year (derived)	
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 SEP 2020
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Height (xxx.x)	169.1 cm
Weight (xxx.x)	83.6 kg
BMI (xxx.x)	29.23607 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	ND - Not Done
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 03:43:11

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 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 03:43:11

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Date of assessment (dd MMM yyyy) 09 SEP 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) _____
Date of last menstruation unknown True

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 15 Feb 2021 03:43:11

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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 03:43:11

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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 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

What was the date of randomization? (dd MMM yyyy) 09 SEP 2020

What was the participant's randomization number? 190371

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 03:43:11

Generated On: 10 Jun 2021 07:59:21

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 03:43:11

Generated On: 10 Jun 2021 07:59:21

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)	09 SEP 2020
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	NOT SPECIFIED
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

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)	09 SEP 2020
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	09 SEP 2020 13:32
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 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 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

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) 9 SEP 2020

What was the treatment time? (00:00-23:59) 13:02 (24 HR)

Treatment Date and Time (derived) 9 SEP 2020 13:02

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (<i>dd MMM yyyy</i>)	09 SEP 2020
Collection time (<i>00:00-23:59</i>)	12:40 (24 HR)
Collection date and time (derived)	09 SEP 2020 12:40

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Collection date (dd MMM yyyy)			09 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:50	09 SEP 2020 12:50
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

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: 10 Jun 2021 07:59:21

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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 13:24

PC Open Date & Time

09 SEP 2020 13:22

PC Close Date & Time

09 SEP 2020 15:52

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.5 °F

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

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

PC Time Stamp	10 SEP 2020 06:25
PC Open Date & Time	09 SEP 2020 16:47
PC Close Date & Time	10 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

10 SEP 2020 18:18

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 18:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.5 °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

12 SEP 2020 14:20

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 12:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 12:15

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 13:24

PC Open Date & Time

09 SEP 2020 13:22

PC Close Date & Time

09 SEP 2020 15:52

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 06:27

PC Open Date & Time

09 SEP 2020 16:47

PC Close Date & Time

10 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 18:21

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

11 SEP 2020 18:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

12 SEP 2020 14:20

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

14 SEP 2020 12:11

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

15 SEP 2020 12:16

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

No ☒

Yes ☐

PC Time stamp	09 SEP 2020 13:25
PC Open Date & Time	09 SEP 2020 13:22
PC Close Date & Time	09 SEP 2020 15:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 06:28
PC Open Date & Time	09 SEP 2020 16:47
PC Close Date & Time	10 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

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 ☒

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 18:22
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

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 ☒

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	11 SEP 2020 18:25
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

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 ☒

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 14:21
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

59 of 2329

EAB) (1725)

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

61 of 2329

EAB) (1725)

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

63 of 2329

EAB) (1725)

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	VISIT2

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

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)	07 OCT 2020
Time of assessment (00:00-23:59)	10:27 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 10:27
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

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)	07 OCT 2020
Time of assessment (00:00-23:59)	13:22 (24 HR)
Vital Signs Date and Time (derived)	07 OCT 2020 13:22
Temperature (xxx.x)	98.0 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3492107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

07 OCT 2020

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

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

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) 7 OCT 2020

What was the treatment time? (00:00-23:59) 12:50 (24 HR)

Treatment Date and Time (derived) 7 OCT 2020 12:50

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

US3492107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

07 OCT 2020

Collection time (00:00-23:59)

11:27 (24 HR)

Collection date and time (derived)

07 OCT 2020 11:27

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Collection date (dd MMM yyyy)			07 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:38	07 OCT 2020 11:38
Nasopharyngeal Swab 2	No		

US3492107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐
No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

07 OCT 2020 13:10

PC Close Date & Time

07 OCT 2020 15:40

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.0 °F

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

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

PC Time Stamp	07 OCT 2020 23:12
PC Open Date & Time	07 OCT 2020 16:35
PC Close Date & Time	08 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

08 OCT 2020 18:46

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 OCT 2020 21:15

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

97.1 °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

10 OCT 2020 12:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

97.5 °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

12 OCT 2020 06:47

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

12 OCT 2020 21:10

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

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.

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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

13 OCT 2020 18:39

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☐

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

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

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

Yes ☐

No ☐

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

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

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

Please select one response below

None ☐

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

07 OCT 2020 13:10

PC Close Date & Time

07 OCT 2020 15:40

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

07 OCT 2020 23:13

PC Open Date & Time

07 OCT 2020 16:35

PC Close Date & Time

08 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

3

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 OCT 2020 18:48

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 OCT 2020 21:16

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

10 OCT 2020 12:07

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

12 OCT 2020 06:48

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

12 OCT 2020 21:11

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

13 OCT 2020 18:39

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

07 OCT 2020 13:10

PC Close Date & Time

07 OCT 2020 15:40

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 23:14
PC Open Date & Time	07 OCT 2020 16:35
PC Close Date & Time	08 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

		Yes <input type="checkbox"/>
PC Time stamp	08 OCT 2020 18:50	
PC Open Date & Time	08 OCT 2020 12:00	
PC Close Date & Time	09 OCT 2020 11:59	

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

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 ☒

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 21:16
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

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 ☒

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 12:07
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

105 of 2329

EAB) (1725)

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 06:48
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

107 of 2329

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	12 OCT 2020 21:11
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

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)

109 of 2329

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 18:40
PC Open Date & Time	13 OCT 2020 12:00
PC Close Date & Time	14 OCT 2020 11:59

US3492107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 NOV 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

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	4 NOV 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	4 NOV 2020 10:30
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 NOV 2020

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

US3492107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 NOV 2020
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	4 NOV 2020 10:40

US3492107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 12:41:38

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 <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 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	16 NOV 2020 09:20:38
Patient Cloud Open Date & Time	16 NOV 2020 00:01
Patient Cloud Close Date & Time	20 NOV 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 75

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 07:09:39

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	27 NOV 2020 17:17:29
Patient Cloud Open Date & Time	27 NOV 2020 00:01
Patient Cloud Close Date & Time	01 DEC 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 DEC 2020 08:43:53
Patient Cloud Open Date & Time	04 DEC 2020 00:01
Patient Cloud Close Date & Time	08 DEC 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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	12 DEC 2020 02:13:32
Patient Cloud Open Date & Time	11 DEC 2020 00:01
Patient Cloud Close Date & Time	15 DEC 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

18 DEC 2020 02:55:46

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

25 DEC 2020 08:20:31

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

01 JAN 2021 09:54:46

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

08 JAN 2021 06:02:11

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	15 JAN 2021 06:05:34
Patient Cloud Open Date & Time	15 JAN 2021 00:01
Patient Cloud Close Date & Time	19 JAN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 JAN 2021 09:59:56
Patient Cloud Open Date & Time	22 JAN 2021 00:01
Patient Cloud Close Date & Time	26 JAN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

29 JAN 2021 10:23:40

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	08 FEB 2021 18:29:49
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

19 FEB 2021 08:41:02

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

01 MAR 2021 19:09:37

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 MAR 2021 10:25:52

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 10:37:24

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

22 MAR 2021 18:20:59

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

26 MAR 2021 08:09:18

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

02 APR 2021 07:12:08

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 APR 2021 18:41:37

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

16 APR 2021 21:18:27

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 06:50:42

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

30 APR 2021 17:58:22

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 contact your study clinic immediately. Click below to confirm that you have read this message and 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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 AUG 2021 00:01
Patient Cloud Close Date & Time	31 AUG 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	05 OCT 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

12 OCT 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Open Date & Time](#)

15 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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°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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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Patient Cloud Close Date & Time	16 NOV 2021 23:59
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US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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="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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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°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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

19 APR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 607

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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°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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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Patient Cloud Close Date & Time	16 AUG 2022 23:59
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US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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°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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	06 SEP 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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="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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

04 OCT 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

11 OCT 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	18 OCT 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

[Patient Cloud Close Date & Time](#)

25 OCT 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

28 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

04 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2022 23:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	11 NOV 2022 00:01
Patient Cloud Close Date & Time	15 NOV 2022 23:59

US3492107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 10 Jun 2021 07:59:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		01 MAR 2021 19:09:49

US3492107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 15 Feb 2021 03:43:11

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 26 Mar 2021 01:43:33

Generated On: 10 Jun 2021 07:59:21

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3492107

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 01:43:33

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Apr 2021 16:25:01

Generated On: 10 Jun 2021 07:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Apr 2021 16:25:01

Generated On: 10 Jun 2021 07:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	08 APR 2021
Time of assessment (00:00-23:59)	10:28 (24 HR)
Vital Signs Date and Time (derived)	08 APR 2021 10:28
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TYMPANIC
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Apr 2021 16:25:01

Generated On: 10 Jun 2021 07:59:21

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.

US3492107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

Collection date (dd MMM yyyy)	08 APR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	10:38 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	08 APR 2021 10:38
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US3492107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3492107

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Date of Contact	12 NOV 2020
Time of Contact	15:00
Date and Time of Contact (derived)	12 NOV 2020 15:00
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input checked="" type="checkbox"/></div> <div>Safety Call<input 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>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" 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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US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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	13 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
O2 Saturation Units	%	
Temperature	97.6 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.9 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
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EAB) (1725)		

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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	15 NOV 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
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 type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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 12 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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	16 NOV 2020	
Assessment Not Done	False	
O2 Saturation	99 %	
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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EAB) (1725)		

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

	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 12 Nov 2020

Form: Symptom Log (5)

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

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"/>

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Date of Visit	12 NOV 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	12 NOV 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

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Visit	Was Saliva Collected?	Date of Collection
Day 3	NA (COVID-19 Negative)	
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)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	12 NOV 2020
Time of assessment (<i>00:00-23:59</i>)	15:00 (24 HR)
Vital Signs Date and Time (derived)	12 NOV 2020 15:00
Height (<i>xxx.x</i>)	ND - Not Done
Weight (<i>xxx.x</i>)	ND - Not Done
Temperature (<i>xxx.x</i>)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	68 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	148 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492107

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 NOV 2020

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

US3492107

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 03:43:10

Generated On: 10 Jun 2021 07:59:21

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

12 NOV 2020

US3492107

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 01:43:33

Generated On: 10 Jun 2021 07:59:21

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID UNBLND_DECIDE

US3492107

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 01:43:33

Generated On: 10 Jun 2021 07:59:21

Date of updated informed consent (<i>dd MMM yyyy</i>)	
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	True
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 checked="" type="radio"/> Amendment 6 or later <input type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	08 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	

US3492107

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 01:43:33

Generated On: 10 Jun 2021 07:59:21

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3492107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 01:43:33

Generated On: 10 Jun 2021 07:59:21

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00 - 23:59)

Collection Date and Time (derived)

US3492107

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Feb 2021 03:43:01

Generated On: 10 Jun 2021 07:59:21

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

AEID	USA-US101-2021-MRNA-1273-P30 1000002
Adverse event	WORSENING OF EXISTING CORONARY ARTERY DISEASE
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)	8 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	15 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input checked="" type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SUBJECT CALLED TO REPORT THAT WAS BEING ADMITTED TO HOSPITAL AFTER ANGIOGRAM SHOWING HIGH DEGREE OF BLOCKAGE IN 3 ARTERIES (90%, 85% AND 65% BUT WAS UNSURE WHICH ARTERIES AFFECTED). PER PI, SHOULD UNBLIND SUBJECT. PI REPORTED THAT SUBJECT HAD RECEIVED ACTIVE PRODUCT. SUBJECT (AND CARDIOLOGY STAFF WHO WAS PRESENT IN ROOM AT TIME OF CALL TO SUBJECT TO UNBLIND) WERE INFORMED. CURRENT STATUS IS UNKNOWN AND TYPE OF SURGERY PLANNED AND DATE ALSO UNKNOWN BUT SUBJECT WILL NOT BE DISCHARGED UNTIL AFTER SURGERY. 10JAN2021 - COVID TEST NEGATIVE

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

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

AEID

Adverse event

FEVER OF UNKNOWN
ETIOLOGY

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)

5 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

6 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 15 Feb 2021 03:43:01

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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) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA/R CAROTID
ARTERY BLOCKAGE

Dose per administration 80

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 (1)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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) _____		
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) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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 2000	
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 (4)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 30

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

If dose unit is Other, specify NOT SPECIFIED

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication VANIQA (EFLORNITHINE
HYDROCHLORIDE)

Prophylaxis Yes ☐
No ☒

Indication FACIAL HAIR

Dose per administration UNK

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

If dose unit is Other, specify NOT SPECIFIED

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 (5)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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)	_____	
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)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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)		26 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)		26 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 (8)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CAD

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

EVERY MORNING PRN

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) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		_____
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 (9)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication WORSENING CAD

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	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)		30 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		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 (10)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication VITAMIN D 3

Prophylaxis Yes ☒
No ☐

Indication SUPPLEMENT

Dose per administration 1,000

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) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication 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 ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 1,000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	5 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) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Name of Medication HYDROCODONE 5/325

Prophylaxis Yes ☐
No ☒

Indication S/P CABG (DUE TO WORSENING CAD)

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 15 Feb 2021 03:43:10

Generated On: 10 Jun 2021 07:59:21

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
8 JAN 2021	ANGIOGRAM	Medical History	
11 JAN 2021	CABG	Adverse Event	

US3492107

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 07:59:21

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

US3492107

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 07:59:21

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 ☐

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	11/JAN/2021 11:11
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

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	04/MAR/2021 13:04
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

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/MAR/2021 09:20
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

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/MAR/2021 01:41
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

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	13/APR/2021 13:31
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

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 16:25:00

Generated On: 10 Jun 2021 07:59:21

SAEID	USA-US101-2021-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	NOVAK
Site Address: Street	808 S. WOOD ST
Site Address: City	CHICAGO
Site Address: State	IL
Site Address: Postal Code	60612
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/APR/2021 10:56
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

US3492107 (Prod: UIC Project WISH CRS)

US3492107

Form: Participant Creation

Generated On: 10 Jun 2021 07:59:21

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
User entered 'US3492107'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:16:32

US3492107

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:11:04

US3492107

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:16:33

US3492107

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[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 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:11:04

US3492107

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'SCRN'	System	10 Sep 2020 18:11:04

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:16:35

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '75'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'YEARS'	System	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '75'	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Female (F)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 07:59:21

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:32:17

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Sep 2020'	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2020'	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Amendment 2 (2)' reason for change:	(b) (4)	
Data Entry Error	Marla Schwarber (b) (4)	25 Sep 2020 17:43:21
User entered 'Amendment 3 (3)'	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:16:33

US3492107

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 07:59:21

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'I'	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:16:59

US3492107

Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 07:59:21

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:13:41

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system vascular disorders NEC, PT: Carotid artery disease, LLT: Carotid artery disease - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:23:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Apr 2021 21:23:35
Data point term sent to Coder	System	12 Apr 2021 20:33:29
Coding entries removed.	Diana Bahena (b) (4)	12 Apr 2021 20:32:32
Signature has been broken.	Diana Bahena (b) (4)	12 Apr 2021 20:32:32
User entered 'CAROTID ARTERY Disease' reason for change: Data Entry Error	Diana Bahena (b) (4)	12 Apr 2021 20:32:32
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Carotid artery occlusion, LLT: Carotid artery occlusion - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:15:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:15:53
Data point term sent to Coder	System	10 Sep 2020 18:14:56
User entered 'carotid artery blockage'	(b) (4), (b) (6)	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 2005'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 2005'	System	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2005'	System	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:14:53

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:27:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:27:01
Data point term sent to Coder	System	10 Nov 2020 16:50:54
Coding entries removed.	Marla Schwarber (b) (4)	10 Nov 2020 16:50:38
User entered 'osteoARTHRITIS of right knee, right hip, lumbar spine' reason for change: Data Entry Error	Marla Schwarber (b) (4)	10 Nov 2020 16:50:38
Query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	06 Nov 2020 08:28:30
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please specify the type of ARTHRITIS (Rheumatoid versus Osteoarthritis) and the location. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	28 Oct 2020 05:23:54
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Arthropathies NEC, PT: Arthritis, LLT: Arthritis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:16:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:16:44
Data point term sent to Coder	System	10 Sep 2020 18:15:57
User entered 'arthritis'	(b) (4), (b) (6)	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:15:19

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:17:49
Data point term sent to Coder	System	10 Sep 2020 18:17:03
User entered 'type 1 diabetes'	(b) (4), (b) (6)	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 1970'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 1970'	System	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '1970'	System	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:16:21

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:17:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Sep 2020 18:17:49
Data point term sent to Coder	System	10 Sep 2020 18:17:04
User entered 'anxiety'	(b) (4), (b) (6)	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 2010'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 2010'	System	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2010'	System	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:16:40

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:13:22
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Oct 2020 15:13:22
Data point term sent to Coder	System	12 Oct 2020 15:12:26
User entered 'post-menopausal'	(b) (4), (b) (6)	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	12 Oct 2020 15:11:43

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
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)	09 Nov 2020 19:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 19:49:35
Data point term sent to Coder	System	09 Nov 2020 19:48:50
User entered 'Hypertension'	Diana Bahena (b) (4)	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	Diana Bahena (b) (4)	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Diana Bahena (b) (4)	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:48:09

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 19:50:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Nov 2020 19:50:35
Data point term sent to Coder	System	09 Nov 2020 19:49:51
User entered 'Hypothyroidism'	Diana Bahena (b) (4)	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	Diana Bahena (b) (4)	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Diana Bahena (b) (4)	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:49:51

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Hypertrichoses, PT: Hypertrichosis, LLT: Facial hair increased - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 07:34:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	17 Nov 2020 07:34:54
Data point term sent to Coder	System	09 Nov 2020 19:50:53
User entered 'Facial Hair'	Diana Bahena (b) (4)	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	Diana Bahena (b) (4)	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Diana Bahena (b) (4)	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Diana Bahena (b) (4)	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Diana Bahena (b) (4)	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	09 Nov 2020 19:50:48

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Spinal stenosis, LLT: Spinal stenosis - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 19:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Nov 2020 19:23:47
Data point term sent to Coder	System	18 Nov 2020 19:23:10
User closed query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) LUMBAR FUSION 2) Spinal stenosis lumbar etc.' (Site from System).	System	18 Nov 2020 19:22:53
Query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) LUMBAR FUSION 2) Spinal stenosis lumbar etc.' answered with 'corrected' (Site from System).	Marla Schwarber (b) (4)	18 Nov 2020 19:22:53
User entered 'SPINAL STENOSIS' reason for change: Data Entry Error	Marla Schwarber (b) (4)	18 Nov 2020 19:22:36
User opened query 'DM-Coding: Please split diagnosis and procedure to report each event separately, example: 1) LUMBAR FUSION 2) Spinal stenosis lumbar etc.' (Site from System).	Coder Import (b) (4)	13 Nov 2020 11:07:43
Data point term sent to Coder	System	10 Nov 2020 16:55:00
User entered 'Spinal stenosis - s/p lumbar fusion'	Marla Schwarber (b) (4)	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 2015'	Marla Schwarber (b) (4)	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Marla Schwarber (b) (4)	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	Marla Schwarber (b) (4)	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 2015'	Marla Schwarber (b) (4)	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Marla Schwarber (b) (4)	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 2015'	System	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2015'	System	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 2015'	System	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2015'	System	10 Nov 2020 16:54:34

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 19:25:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Nov 2020 19:25:47
Data point term sent to Coder	System	18 Nov 2020 19:25:13
User entered 'Lumbar spinal fusion'	Marla Schwarber (b) (4)	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 2015'	Marla Schwarber (b) (4)	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Marla Schwarber (b) (4)	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	Marla Schwarber (b) (4)	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'un UNK 2015'	Marla Schwarber (b) (4)	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Marla Schwarber (b) (4)	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 2015'	System	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2015'	System	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'Jan 2015'	System	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '2015'	System	18 Nov 2020 19:24:13

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User coded data point as SOC: Eye disorders, HLGT: Ocular structural change, deposit and degeneration NEC, HLT: Retinal structural change, deposit and degeneration, PT: Retinal detachment, LLT: Detached retina - version MedDRA\\23.0.	(b) (4)	07 Dec 2020 18:30:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 18:30:00
Data point term sent to Coder	(b) (4)	07 Dec 2020 18:29:01
User entered 'detached retina'	System	07 Dec 2020 18:28:29
	Lorna Sanchez McCann	
	(b) (4)	

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Lorna Sanchez McCann (b) (4)	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	Lorna Sanchez McCann (b) (4)	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Lorna Sanchez McCann (b) (4)	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Lorna Sanchez McCann (b) (4)	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Medical History (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	07 Dec 2020 18:28:29

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	15 Sep 2020 12:56:04
Query 'Data is required. Please provide.' answered with 'time was not written in the chart' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 18:38:25
User opened query 'Data is required. Please provide.' System (Site from System).		10 Sep 2020 18:38:12
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered empty.	System	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '169.1' cm	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12
DataPoint set to visible.	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '83.6' kg	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12
DataPoint set to visible.	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered '29.23607'	System	10 Sep 2020 18:38:12
DataPoint set to visible.	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'kg/m2'	System	10 Sep 2020 18:38:12
DataPoint set to visible.	System	09 Sep 2020 18:17:14

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 14:03:10
Query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' answered with '-----corrected-----' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 20:23:18
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	05 Jan 2021 20:23:15
User opened query 'Per CDM: Temperature is recorded as ND but Route of measurement is present, not blank. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:38:47
User entered 'Other (Other)'	(b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'bpm'	System	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'breaths/min'	System	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'mmHg'	System	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User entered 'mmHg'	System	10 Sep 2020 18:38:12

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04

US3492107

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04

US3492107

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:36

US3492107

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:38:36

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Oct 2020 14:56:06
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 15:11:54
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Oct 2020 06:13:38
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 07:59:21

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:01

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

US3492107

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

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Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 07:59:21

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:11:04
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:33:20

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:16:43

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:16:43

US3492107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:16:43

US3492107

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'VISIT1'	System	09 Sep 2020 18:16:43

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:20:42

US3492107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '190371'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:20:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	09 Sep 2020 17:20:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:28:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:28:36

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:28:36

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Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:28:36

US3492107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 17:28:36

US3492107

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 07:59:21

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:50:37
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:50:36

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:01:31
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4)	19 Oct 2020 17:17:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:17:50
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:35:48
User entered '169.1' cm reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:17:50
User entered '83.6' kg reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:01:31
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4)	19 Oct 2020 17:17:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:17:50
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:35:48
User entered '169.1' cm reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:17:50
User entered '83.6' kg reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:37:06
User entered '09 Sep 2020' reason for change: Data Entry Error	System	10 Sep 2020 18:37:06
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 18:12:44
User entered empty.	System	10 Sep 2020 18:12:44
	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	15 Sep 2020 12:55:52
Query 'Data is required. Please provide.' answered with 'the time was not written in the chart' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 18:36:29
User opened query 'Data is required. Please provide.' System (Site from System).		10 Sep 2020 18:12:44
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered empty.	System	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:37:06
User entered '97.5' F reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:12:44
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'not specified' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:37:06
User entered '63' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:12:44
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'bpm'	System	10 Sep 2020 18:37:06
User entered empty.	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:37:06
User entered '18' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:12:44
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'breaths/min'	System	10 Sep 2020 18:37:06
User entered empty.	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:37:06
User entered '123' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:12:44
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	10 Sep 2020 18:37:06
User entered empty.	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	10 Sep 2020 18:37:06
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	10 Sep 2020 18:37:06
User entered '72' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:06
User opened query 'Data is required. Please provide.' (Site from System).	System	10 Sep 2020 18:12:44
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	10 Sep 2020 18:37:06
User entered empty.	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:21

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 08:01:31
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4)	19 Oct 2020 17:17:56
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:17:50
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for HEIGHT and WEIGHT at Visit 1 if Screening and Visit 1 were done on the same day. Please update data fields accordingly.' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 13:35:48
User entered '169.1' cm reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 07:59:21

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Oct 2020 17:17:50
User entered '83.6' kg reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:37:31
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '13:32'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '09 Sep 2020 13:32'	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '64'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'bpm'	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '17'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'breaths/min'	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '132'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '77'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	10 Sep 2020 18:12:44

US3492107

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:35:03

US3492107

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:35:03

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'MRNA-1273 OR PLACEBO'	System	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '9 Sep 2020'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '13:02'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '9 Sep 2020 13:02'	System	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'ONCE'	System	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'INTRAMUSCULAR'	System	09 Sep 2020 18:18:09

US3492107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:23

US3492107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '09 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:23

US3492107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12:40'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:23

US3492107

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '09 Sep 2020 12:40'	System	10 Sep 2020 18:34:23

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:59:21

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	(b) (4)	10 Sep 2020 18:34:46
Query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' answered by data change (Site from System).	System	10 Sep 2020 18:34:46
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	10 Sep 2020 18:34:46
User opened query 'A sample was collected below, however, Collection date is missing. Please review and reconcile.' (Site from System).	System	10 Sep 2020 18:34:38
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12:50'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '09 Sep 2020 12:50'	System	10 Sep 2020 18:34:46
User entered empty.	System	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered empty.	System	10 Sep 2020 18:34:38

US3492107

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Sep 2020 18:18:33

US3492107

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	09 Sep 2020 18:18:33

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:23:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa28d09e-8b09-475a-b451-bce8f229566b' User entered 'Yes (Y)'	System	09 Sep 2020 18:24:06
	System	09 Sep 2020 18:24:06

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:23:41', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa28d09e-8b09-475a-b451-bce8f229566b' User entered '98.1'	System	09 Sep 2020 18:24:06
	System	09 Sep 2020 18:24:06

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:23:51', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa28d09e-8b09-475a-b451-bce8f229566b'	System	09 Sep 2020 18:24:06
User entered 'No (N)'	System	09 Sep 2020 18:24:06

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:04', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa28d09e-8b09-475a-b451-bce8f229566b' User entered '09 Sep 2020 13:24'	System	09 Sep 2020 18:24:06
	System	09 Sep 2020 18:24:06

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 15:52'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:24:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '761d0bff-52f9-4579-b485-0c499f1c67c7'	System	10 Sep 2020 11:25:21
User entered 'Yes (Y)'	System	10 Sep 2020 11:25:21

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:24:58', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '761d0bff-52f9-4579-b485-0c499f1c67c7' User entered '97.5'	System	10 Sep 2020 11:25:21
	System	10 Sep 2020 11:25:21

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:25:03', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '761d0bff-52f9-4579-b485-0c499f1c67c7'	System	10 Sep 2020 11:25:21
User entered 'No (N)'	System	10 Sep 2020 11:25:21

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:25:15', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '761d0bff-52f9-4579-b485-0c499f1c67c7' User entered '10 Sep 2020 06:25'	System	10 Sep 2020 11:25:21
	System	10 Sep 2020 11:25:21

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 16:47'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 2'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:03', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2e58f20-1e3e-4d04-a535-57b41b09901c' User entered 'Yes (Y)'	System	10 Sep 2020 23:18:28
	System	10 Sep 2020 23:18:28

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:13', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2e58f20-1e3e-4d04-a535-57b41b09901c' User entered '97.5'	System	10 Sep 2020 23:18:28
	System	10 Sep 2020 23:18:28

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2e58f20-1e3e-4d04-a535-57b41b09901c' User entered 'No (N)'	System	10 Sep 2020 23:18:28
	System	10 Sep 2020 23:18:28

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2e58f20-1e3e-4d04-a535-57b41b09901c' User entered '10 Sep 2020 18:18'	System	10 Sep 2020 23:18:28
	System	10 Sep 2020 23:18:28

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 3'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:13', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ce8b00d9-c4f7-4150-be40-c20c20d709de' User entered 'Yes (Y)'	System	11 Sep 2020 23:24:30
	System	11 Sep 2020 23:24:30

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ce8b00d9-c4f7-4150-be40-c20c20d709de' User entered '98.2'	System	11 Sep 2020 23:24:30
	System	11 Sep 2020 23:24:30

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ce8b00d9-c4f7-4150-be40-c20c20d709de' User entered 'No (N)'	System	11 Sep 2020 23:24:30
	System	11 Sep 2020 23:24:30

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ce8b00d9-c4f7-4150-be40-c20c20d709de' User entered '11 Sep 2020 18:24'	System	11 Sep 2020 23:24:30
	System	11 Sep 2020 23:24:30

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 4'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:19:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6dc6258a-3aad-476e-b99f-1e926b6a33a3' User entered 'Yes (Y)'	System	12 Sep 2020 19:20:10
	System	12 Sep 2020 19:20:10

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:19:57', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6dc6258a-3aad-476e-b99f-1e926b6a33a3' User entered '98.5'	System	12 Sep 2020 19:20:10
	System	12 Sep 2020 19:20:10

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6dc6258a-3aad-476e-b99f-1e926b6a33a3'	System	12 Sep 2020 19:20:10
User entered 'No (N)'	System	12 Sep 2020 19:20:10

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:08', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6dc6258a-3aad-476e-b99f-1e926b6a33a3' User entered '12 Sep 2020 14:20'	System	12 Sep 2020 19:20:10
	System	12 Sep 2020 19:20:10

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 5'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6927575a-838d-455d-9806-3a241f248ab9' User entered 'Yes (Y)'	System	13 Sep 2020 17:02:01
	System	13 Sep 2020 17:02:01

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6927575a-838d-455d-9806-3a241f248ab9' User entered '98.2'	System	13 Sep 2020 17:02:01
	System	13 Sep 2020 17:02:01

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:20', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6927575a-838d-455d-9806-3a241f248ab9' User entered 'No (N)'	System	13 Sep 2020 17:02:01
	System	13 Sep 2020 17:02:01

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6927575a-838d-455d-9806-3a241f248ab9' User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:01
	System	13 Sep 2020 17:02:01

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 6'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f0442cc9-dfdf-430d-8052-39d205037813' User entered 'Yes (Y)'	System	14 Sep 2020 17:11:33
	System	14 Sep 2020 17:11:33

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:20', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f0442cc9-dfdf-430d-8052-39d205037813' User entered '97.6'	System	14 Sep 2020 17:11:33
	System	14 Sep 2020 17:11:33

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f0442cc9-dfdf-430d-8052-39d205037813' User entered 'No (N)'	System	14 Sep 2020 17:11:33
	System	14 Sep 2020 17:11:33

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f0442cc9-dfdf-430d-8052-39d205037813' User entered '14 Sep 2020 12:11'	System	14 Sep 2020 17:11:33
	System	14 Sep 2020 17:11:33

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 7'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:21', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '2ab7fe31-becb-4d69-b5b0-1059e72e62fd' User entered 'Yes (Y)'	System	15 Sep 2020 17:15:39
	System	15 Sep 2020 17:15:39

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '2ab7fe31-becb-4d69-b5b0-1059e72e62fd' User entered '97.8'	System	15 Sep 2020 17:15:39
	System	15 Sep 2020 17:15:39

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:31', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '2ab7fe31-becb-4d69-b5b0-1059e72e62fd' User entered 'No (N)'	System	15 Sep 2020 17:15:39
	System	15 Sep 2020 17:15:39

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:34', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '2ab7fe31-becb-4d69-b5b0-1059e72e62fd' User entered '15 Sep 2020 12:15'	System	15 Sep 2020 17:15:39
	System	15 Sep 2020 17:15:39

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '44bda0cd-a18d-48b4-9c0d-3683b0cff5c9' User entered 'None (1)'	System	09 Sep 2020 18:24:42
	System	09 Sep 2020 18:24:42

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '44bda0cd-a18d-48b4-9c0d-3683b0cff5c9' User entered 'No (N)'	System	09 Sep 2020 18:24:42
	System	09 Sep 2020 18:24:42

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '44bda0cd-a18d-48b4-9c0d-3683b0cff5c9' User entered 'No (N)'	System	09 Sep 2020 18:24:42
	System	09 Sep 2020 18:24:42

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:35', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '44bda0cd-a18d-48b4-9c0d-3683b0cff5c9' User entered 'None (1)'	System	09 Sep 2020 18:24:42
	System	09 Sep 2020 18:24:42

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:39', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '44bda0cd-a18d-48b4-9c0d-3683b0cff5c9' User entered '09 Sep 2020 13:24'	System	09 Sep 2020 18:24:42
	System	09 Sep 2020 18:24:42

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 15:52'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:26:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '887a9690-57fa-41ef-a277-066c5002e617'	System	10 Sep 2020 11:27:22
User entered 'None (1)'	System	10 Sep 2020 11:27:22

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:26:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '887a9690-57fa-41ef-a277-066c5002e617' User entered 'No (N)'	System	10 Sep 2020 11:27:22
	System	10 Sep 2020 11:27:22

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:26:33', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '887a9690-57fa-41ef-a277-066c5002e617' User entered 'No (N)'	System	10 Sep 2020 11:27:22
	System	10 Sep 2020 11:27:22

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:27:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '887a9690-57fa-41ef-a277-066c5002e617'	System	10 Sep 2020 11:27:22
User entered 'None (1)'	System	10 Sep 2020 11:27:22

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:27:20', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '887a9690-57fa-41ef-a277-066c5002e617' User entered '10 Sep 2020 06:27'	System	10 Sep 2020 11:27:22
	System	10 Sep 2020 11:27:22

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 16:47'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 2'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:39', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '18c047db-3d7e-44c4-927b-059fbaeb6258'	System	10 Sep 2020 23:21:44
User entered 'Does not interfere with activity (2)'	System	10 Sep 2020 23:21:44

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '18c047db-3d7e-44c4-927b-059fbaeb6258' User entered 'No (N)'	System	10 Sep 2020 23:21:44
	System	10 Sep 2020 23:21:44

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:18:50', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '18c047db-3d7e-44c4-927b-059fbaeb6258' User entered 'Yes (Y)'	System	10 Sep 2020 23:21:44
	System	10 Sep 2020 23:21:44

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:21:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '18c047db-3d7e-44c4-927b-059fbaeb6258'	System	10 Sep 2020 23:21:44
User entered '3'	System	10 Sep 2020 23:21:44

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:21:34', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '18c047db-3d7e-44c4-927b-059fbaeb6258'	System	10 Sep 2020 23:21:44
User entered 'None (1)'	System	10 Sep 2020 23:21:44

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:21:40', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '18c047db-3d7e-44c4-927b-059fbaeb6258' User entered '10 Sep 2020 18:21'	System	10 Sep 2020 23:21:44
	System	10 Sep 2020 23:21:44

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 3'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:42', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c93b174d-d501-4083-98b9-85d1860212a6'	System	11 Sep 2020 23:25:01
User entered 'None (1)'	System	11 Sep 2020 23:25:01

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c93b174d-d501-4083-98b9-85d1860212a6' User entered 'No (N)'	System	11 Sep 2020 23:25:01
	System	11 Sep 2020 23:25:01

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c93b174d-d501-4083-98b9-85d1860212a6' User entered 'No (N)'	System	11 Sep 2020 23:25:01
	System	11 Sep 2020 23:25:01

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:55', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c93b174d-d501-4083-98b9-85d1860212a6'	System	11 Sep 2020 23:25:01
User entered 'None (1)'	System	11 Sep 2020 23:25:01

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:24:59', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c93b174d-d501-4083-98b9-85d1860212a6' User entered '11 Sep 2020 18:24'	System	11 Sep 2020 23:25:01
	System	11 Sep 2020 23:25:01

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 4'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:22', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '8fb1a9c2-c3c4-447d-a2d3-eab967abd606'	System	12 Sep 2020 19:20:58
User entered 'None (1)'	System	12 Sep 2020 19:20:58

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:25', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '8fb1a9c2-c3c4-447d-a2d3-eab967abd606' User entered 'No (N)'	System	12 Sep 2020 19:20:58
	System	12 Sep 2020 19:20:58

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:48', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '8fb1a9c2-c3c4-447d-a2d3-eab967abd606' User entered 'No (N)'	System	12 Sep 2020 19:20:58
	System	12 Sep 2020 19:20:58

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:52', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '8fb1a9c2-c3c4-447d-a2d3-eab967abd606'	System	12 Sep 2020 19:20:58
User entered 'None (1)'	System	12 Sep 2020 19:20:58

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:20:56', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '8fb1a9c2-c3c4-447d-a2d3-eab967abd606'	System	12 Sep 2020 19:20:58
User entered '12 Sep 2020 14:20'	System	12 Sep 2020 19:20:58

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 5'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:31', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '05988acf-ddc1-4445-98fc-5174089dc0d4'	System	13 Sep 2020 17:02:25
User entered 'None (1)'	System	13 Sep 2020 17:02:25

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:34', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '05988acf-ddc1-4445-98fc-5174089dc0d4' User entered 'No (N)'	System	13 Sep 2020 17:02:25
	System	13 Sep 2020 17:02:25

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:37', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '05988acf-ddc1-4445-98fc-5174089dc0d4' User entered 'No (N)'	System	13 Sep 2020 17:02:25
	System	13 Sep 2020 17:02:25

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:40', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '05988acf-ddc1-4445-98fc-5174089dc0d4'	System	13 Sep 2020 17:02:25
User entered 'None (1)'	System	13 Sep 2020 17:02:25

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '05988acf-ddc1-4445-98fc-5174089dc0d4' User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:25
	System	13 Sep 2020 17:02:25

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 6'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4a52b8f6-ad11-4903-b3b6-f30b0361c5a6'	System	14 Sep 2020 17:11:45
User entered 'None (1)'	System	14 Sep 2020 17:11:45

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:35', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4a52b8f6-ad11-4903-b3b6-f30b0361c5a6' User entered 'No (N)'	System	14 Sep 2020 17:11:45
	System	14 Sep 2020 17:11:45

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:38', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4a52b8f6-ad11-4903-b3b6-f30b0361c5a6' User entered 'No (N)'	System	14 Sep 2020 17:11:45
	System	14 Sep 2020 17:11:45

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:41', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4a52b8f6-ad11-4903-b3b6-f30b0361c5a6'	System	14 Sep 2020 17:11:45
User entered 'None (1)'	System	14 Sep 2020 17:11:45

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:44', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4a52b8f6-ad11-4903-b3b6-f30b0361c5a6' User entered '14 Sep 2020 12:11'	System	14 Sep 2020 17:11:45
	System	14 Sep 2020 17:11:45

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 7'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:45', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7c9722d2-ed11-4849-b7fb-da7ce39bdc22'	System	15 Sep 2020 17:16:05
User entered 'None (1)'	System	15 Sep 2020 17:16:05

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7c9722d2-ed11-4849-b7fb-da7ce39bdc22' User entered 'No (N)'	System	15 Sep 2020 17:16:05
	System	15 Sep 2020 17:16:05

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7c9722d2-ed11-4849-b7fb-da7ce39bdc22' User entered 'No (N)'	System	15 Sep 2020 17:16:05
	System	15 Sep 2020 17:16:05

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:15:52', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7c9722d2-ed11-4849-b7fb-da7ce39bdc22'	System	15 Sep 2020 17:16:05
User entered 'None (1)'	System	15 Sep 2020 17:16:05

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:02', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7c9722d2-ed11-4849-b7fb-da7ce39bdc22' User entered '15 Sep 2020 12:16'	System	15 Sep 2020 17:16:05
	System	15 Sep 2020 17:16:05

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'None (0)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:50', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'None (0)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:53', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'None (0)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:24:57', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'None (0)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:25:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'None (0)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:25:04', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'None (0)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:25:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered 'No (N)'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-09T13:25:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '047af2c7-ac2a-4a60-ad17-d3fc546b6ca6' User entered '09 Sep 2020 13:25'	System	09 Sep 2020 18:25:19
	System	09 Sep 2020 18:25:19

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 13:22'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 15:52'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 1, after vaccination (at home)'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:27:54', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97'	System	10 Sep 2020 11:28:52
User entered 'No interference with activity (1)'	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:08', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97'	System	10 Sep 2020 11:28:52
User entered 'No interference with activity (1)'	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:17', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97' User entered 'None (0)'	System	10 Sep 2020 11:28:52
	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97' User entered 'None (0)'	System	10 Sep 2020 11:28:52
	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97' User entered 'None (0)'	System	10 Sep 2020 11:28:52
	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:35', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97' User entered 'None (0)'	System	10 Sep 2020 11:28:52
	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:44', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97' User entered 'No (N)'	System	10 Sep 2020 11:28:52
	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T06:28:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b6079419-63e1-411f-ae8c-855cf647ff97' User entered '10 Sep 2020 06:28'	System	10 Sep 2020 11:28:52
	System	10 Sep 2020 11:28:52

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Sep 2020 16:47'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 2'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:21:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11' User entered 'None (0)'	System	10 Sep 2020 23:22:32
	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:21:57', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11'	System	10 Sep 2020 23:22:32
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:22:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11' User entered 'None (0)'	System	10 Sep 2020 23:22:32
	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:22:09', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11'	System	10 Sep 2020 23:22:32
User entered 'No interference with activity (1)'	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:22:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11' User entered 'None (0)'	System	10 Sep 2020 23:22:32
	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:22:17', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11' User entered 'None (0)'	System	10 Sep 2020 23:22:32
	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:22:26', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11'	System	10 Sep 2020 23:22:32
User entered 'No (N)'	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-10T18:22:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '35aec884-c74f-4ee4-96f1-d66b7d175f11' User entered '10 Sep 2020 18:22'	System	10 Sep 2020 23:22:32
	System	10 Sep 2020 23:22:32

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 3'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered 'None (0)'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:22', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87'	System	11 Sep 2020 23:25:48
User entered 'No interference with activity (1)'	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:26', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered 'None (0)'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:29', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered 'None (0)'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered 'None (0)'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:34', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered 'None (0)'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:39', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered 'No (N)'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-11T18:25:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5f8dd53f-aaf3-4194-b008-5ce79cbfcb87' User entered '11 Sep 2020 18:25'	System	11 Sep 2020 23:25:48
	System	11 Sep 2020 23:25:48

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 4'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered 'None (0)'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:07', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered 'None (0)'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:10', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered 'None (0)'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:13', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered 'None (0)'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered 'None (0)'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:20', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered 'None (0)'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605'	System	12 Sep 2020 19:21:29
User entered 'No (N)'	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-12T14:21:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '85f603d1-d148-46b8-9bdc-68928e01c605' User entered '12 Sep 2020 14:21'	System	12 Sep 2020 19:21:29
	System	12 Sep 2020 19:21:29

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 5'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:48', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'None (0)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:52', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'None (0)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:01:57', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'None (0)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:02:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'None (0)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:02:03', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'None (0)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:02:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'None (0)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:02:09', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered 'No (N)'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-13T12:02:13', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'bbe540c6-ec15-49df-9b06-04cb2951d6fd' User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:02:53
	System	13 Sep 2020 17:02:53

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 6'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:48', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'None (0)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:51', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'None (0)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:53', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'None (0)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:56', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'None (0)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:11:58', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'None (0)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:12:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'None (0)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:12:04', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88' User entered 'No (N)'	System	14 Sep 2020 17:12:10
	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-14T12:12:07', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '689bdc54-0389-4456-b35b-30a5bc251b88'	System	14 Sep 2020 17:12:10
User entered '14 Sep 2020 12:12'	System	14 Sep 2020 17:12:10

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '15 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 7'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered 'None (0)'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:09', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered 'None (0)'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered 'None (0)'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered 'None (0)'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered 'None (0)'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:18', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered 'None (0)'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:21', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc'	System	15 Sep 2020 17:16:28
User entered 'No (N)'	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-09-15T12:16:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f2fbf480-4ddb-49b7-a4c8-cabf941e5afc' User entered '15 Sep 2020 12:16'	System	15 Sep 2020 17:16:28
	System	15 Sep 2020 17:16:28

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '15 Sep 2020 12:00'	System	09 Sep 2020 18:18:09

US3492107

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '16 Sep 2020 11:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Addis Mekonnen (b) (4)	16 Sep 2020 19:35:56

US3492107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '16 Sep 2020'	Addis Mekonnen (b) (4)	16 Sep 2020 19:35:56

US3492107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Addis Mekonnen (b) (4)	16 Sep 2020 19:35:56

US3492107

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Addis Mekonnen (b) (4)	16 Sep 2020 19:35:56

US3492107

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Addis Mekonnen (b) (4)	16 Sep 2020 19:36:00

US3492107

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	16 Sep 2020 19:36:00

US3492107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Elena Llinas (b) (4)	23 Sep 2020 20:01:48

US3492107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '23 Sep 2020'	Elena Llinas (b) (4)	23 Sep 2020 20:01:48

US3492107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4)	23 Sep 2020 20:01:48

US3492107

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Elena Llinas (b) (4)	23 Sep 2020 20:01:48

US3492107

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Elena Llinas (b) (4)	23 Sep 2020 20:01:52

US3492107

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	23 Sep 2020 20:01:52

US3492107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:08:31

US3492107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '30 Sep 2020'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:08:31

US3492107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:08:31

US3492107

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:08:31

US3492107

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Sep 2020 17:08:35

US3492107

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	30 Sep 2020 17:08:35

US3492107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:34:58

US3492107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:34:58

US3492107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 15:34:58

US3492107

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'VISIT2'	System	07 Oct 2020 15:34:58

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '10:27'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '07 Oct 2020 10:27'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '72'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'bpm'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'breaths/min'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '137'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '78'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '13:22'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '07 Oct 2020 13:22'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '98.0' F	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '67'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'bpm'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '16'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'breaths/min'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '128'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '79'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	08 Oct 2020 13:35:45

US3492107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:34:40

US3492107

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:34:40

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '7 Oct 2020'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12:50'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '7 Oct 2020 12:50'	System	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'ONCE'	System	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 07:59:21

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 17:53:07

US3492107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:54

US3492107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:54

US3492107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '11:27'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:35:54

US3492107

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '07 Oct 2020 11:27'	System	08 Oct 2020 13:35:54

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 07:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '07 Oct 2020'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '11:38'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '07 Oct 2020 11:38'	System	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered empty.	System	08 Oct 2020 13:36:12

US3492107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Oct 2020 17:53:16

US3492107

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	07 Oct 2020 17:53:16

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 13:10'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 15:40'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:12:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b0591286-9534-4aba-9a7e-ebcfbdddbee34' User entered 'Yes (Y)'	System	08 Oct 2020 04:12:54
	System	08 Oct 2020 04:12:54

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:12:42', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b0591286-9534-4aba-9a7e-ebcfbdddbee34' User entered '98.0'	System	08 Oct 2020 04:12:54
	System	08 Oct 2020 04:12:54

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:12:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b0591286-9534-4aba-9a7e-ebcfbdddbee34' User entered 'No (N)'	System	08 Oct 2020 04:12:54
	System	08 Oct 2020 04:12:54

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:12:52', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b0591286-9534-4aba-9a7e-ebcfbdddbee34' User entered '07 Oct 2020 23:12'	System	08 Oct 2020 04:12:54
	System	08 Oct 2020 04:12:54

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 16:35'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 2'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:46:17', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7e872a79-2ea2-47f4-945d-8ba71c634967' User entered 'Yes (Y)'	System	08 Oct 2020 23:46:59
	System	08 Oct 2020 23:46:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:46:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7e872a79-2ea2-47f4-945d-8ba71c634967' User entered '97.5'	System	08 Oct 2020 23:46:59
	System	08 Oct 2020 23:46:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:46:54', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7e872a79-2ea2-47f4-945d-8ba71c634967'	System	08 Oct 2020 23:46:59
User entered 'No (N)'	System	08 Oct 2020 23:46:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:46:58', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7e872a79-2ea2-47f4-945d-8ba71c634967' User entered '08 Oct 2020 18:46'	System	08 Oct 2020 23:46:59
	System	08 Oct 2020 23:46:59

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 3'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:13:53', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '11f511ff-6963-420e-8263-1270f3675faf' User entered 'Yes (Y)'	System	10 Oct 2020 02:15:37
	System	10 Oct 2020 02:15:37

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:14:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '11f511ff-6963-420e-8263-1270f3675faf' User entered '97.6'	System	10 Oct 2020 02:15:37
	System	10 Oct 2020 02:15:37

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:15:25', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '11f511ff-6963-420e-8263-1270f3675faf' User entered 'No (N)'	System	10 Oct 2020 02:15:37
	System	10 Oct 2020 02:15:37

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:15:31', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '11f511ff-6963-420e-8263-1270f3675faf' User entered '09 Oct 2020 21:15'	System	10 Oct 2020 02:15:37
	System	10 Oct 2020 02:15:37

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 4'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:06:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ff1f51a4-3198-4709-a433-ed6dd4e8deab' User entered 'Yes (Y)'	System	10 Oct 2020 17:07:06
	System	10 Oct 2020 17:07:06

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:06:54', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ff1f51a4-3198-4709-a433-ed6dd4e8deab' User entered '97.1'	System	10 Oct 2020 17:07:06
	System	10 Oct 2020 17:07:06

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:06:59', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ff1f51a4-3198-4709-a433-ed6dd4e8deab' User entered 'No (N)'	System	10 Oct 2020 17:07:06
	System	10 Oct 2020 17:07:06

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:02', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ff1f51a4-3198-4709-a433-ed6dd4e8deab' User entered '10 Oct 2020 12:07'	System	10 Oct 2020 17:07:06
	System	10 Oct 2020 17:07:06

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 5'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:47:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '67deed5b-a162-437e-be56-cf0531ba40b5' User entered 'Yes (Y)'	System	12 Oct 2020 11:48:04
	System	12 Oct 2020 11:48:04

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:47:50', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '67deed5b-a162-437e-be56-cf0531ba40b5' User entered '97.5'	System	12 Oct 2020 11:48:04
	System	12 Oct 2020 11:48:04

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:47:56', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '67deed5b-a162-437e-be56-cf0531ba40b5'	System	12 Oct 2020 11:48:04
User entered 'No (N)'	System	12 Oct 2020 11:48:04

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:47:59', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '67deed5b-a162-437e-be56-cf0531ba40b5' User entered '12 Oct 2020 06:47'	System	12 Oct 2020 11:48:04
	System	12 Oct 2020 11:48:04

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 6'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:21', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1dcca2d1-16d2-4051-870e-a51f765f81a6'	System	13 Oct 2020 02:10:45
User entered 'Yes (Y)'	System	13 Oct 2020 02:10:45

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:33', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1dcca2d1-16d2-4051-870e-a51f765f81a6' User entered '97.7'	System	13 Oct 2020 02:10:45
	System	13 Oct 2020 02:10:45

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:38', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1dcca2d1-16d2-4051-870e-a51f765f81a6'	System	13 Oct 2020 02:10:45
User entered 'No (N)'	System	13 Oct 2020 02:10:45

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:41', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1dcca2d1-16d2-4051-870e-a51f765f81a6'	System	13 Oct 2020 02:10:45
User entered '12 Oct 2020 21:10'	System	13 Oct 2020 02:10:45

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 7'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:18', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '185b8ff2-b674-4eba-b0f7-c1711edc8e2d' User entered 'Yes (Y)'	System	13 Oct 2020 23:39:36
	System	13 Oct 2020 23:39:36

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '185b8ff2-b674-4eba-b0f7-c1711edc8e2d' User entered '97.6'	System	13 Oct 2020 23:39:36
	System	13 Oct 2020 23:39:36

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '185b8ff2-b674-4eba-b0f7-c1711edc8e2d'	System	13 Oct 2020 23:39:36
User entered 'No (N)'	System	13 Oct 2020 23:39:36

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '185b8ff2-b674-4eba-b0f7-c1711edc8e2d' User entered '13 Oct 2020 18:39'	System	13 Oct 2020 23:39:36
	System	13 Oct 2020 23:39:36

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 13:10'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 15:40'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'df25b3b3-9c79-44b3-9906-50fea7ea7a45'	System	08 Oct 2020 04:13:37
User entered 'None (1)'	System	08 Oct 2020 04:13:37

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:18', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'df25b3b3-9c79-44b3-9906-50fea7ea7a45'	System	08 Oct 2020 04:13:37
User entered 'No (N)'	System	08 Oct 2020 04:13:37

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:22', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'df25b3b3-9c79-44b3-9906-50fea7ea7a45'	System	08 Oct 2020 04:13:37
User entered 'No (N)'	System	08 Oct 2020 04:13:37

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:29', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'df25b3b3-9c79-44b3-9906-50fea7ea7a45'	System	08 Oct 2020 04:13:37
User entered 'None (1)'	System	08 Oct 2020 04:13:37

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:33', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'df25b3b3-9c79-44b3-9906-50fea7ea7a45' User entered '07 Oct 2020 23:13'	System	08 Oct 2020 04:13:37
	System	08 Oct 2020 04:13:37

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 16:35'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 2'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:47:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '757eaf16-5faf-48f4-945d-137aaaebd599'	System	08 Oct 2020 23:49:02
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 23:49:02

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:47:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '757eaf16-5faf-48f4-945d-137aaebd599'	System	08 Oct 2020 23:49:02
User entered 'No (N)'	System	08 Oct 2020 23:49:02

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:47:17', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '757eaf16-5faf-48f4-945d-137aaebd599'	System	08 Oct 2020 23:49:02
User entered 'Yes (Y)'	System	08 Oct 2020 23:49:02

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:48:41', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '757eaf16-5faf-48f4-945d-137aaebd599'	System	08 Oct 2020 23:49:02
User entered '3'	System	08 Oct 2020 23:49:02

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:48:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '757eaf16-5faf-48f4-945d-137aaebd599'	System	08 Oct 2020 23:49:02
User entered 'None (1)'	System	08 Oct 2020 23:49:02

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:48:56', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '757eaf16-5faf-48f4-945d-137aaebd599' User entered '08 Oct 2020 18:48'	System	08 Oct 2020 23:49:02
	System	08 Oct 2020 23:49:02

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 3'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:15:37', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '0eb62855-cf0a-4f76-8e11-9a7f70545a25'	System	10 Oct 2020 02:16:05
User entered 'None (1)'	System	10 Oct 2020 02:16:05

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:15:40', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '0eb62855-cf0a-4f76-8e11-9a7f70545a25' User entered 'No (N)'	System	10 Oct 2020 02:16:05
	System	10 Oct 2020 02:16:05

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:15:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '0eb62855-cf0a-4f76-8e11-9a7f70545a25'	System	10 Oct 2020 02:16:05
User entered 'No (N)'	System	10 Oct 2020 02:16:05

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:15:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '0eb62855-cf0a-4f76-8e11-9a7f70545a25'	System	10 Oct 2020 02:16:05
User entered 'None (1)'	System	10 Oct 2020 02:16:05

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:03', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '0eb62855-cf0a-4f76-8e11-9a7f70545a25' User entered '09 Oct 2020 21:16'	System	10 Oct 2020 02:16:05
	System	10 Oct 2020 02:16:05

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 4'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:09', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08819e02-0df1-400d-a5fe-82a23396965d' User entered 'None (1)'	System	10 Oct 2020 17:07:25
	System	10 Oct 2020 17:07:25

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:12', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08819e02-0df1-400d-a5fe-82a23396965d' User entered 'No (N)'	System	10 Oct 2020 17:07:25
	System	10 Oct 2020 17:07:25

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:15', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08819e02-0df1-400d-a5fe-82a23396965d' User entered 'No (N)'	System	10 Oct 2020 17:07:25
	System	10 Oct 2020 17:07:25

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:18', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08819e02-0df1-400d-a5fe-82a23396965d' User entered 'None (1)'	System	10 Oct 2020 17:07:25
	System	10 Oct 2020 17:07:25

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:22', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08819e02-0df1-400d-a5fe-82a23396965d' User entered '10 Oct 2020 12:07'	System	10 Oct 2020 17:07:25
	System	10 Oct 2020 17:07:25

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 5'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:07', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3bf20201-c317-4d30-b481-dd78e1483204'	System	12 Oct 2020 11:48:26
User entered 'None (1)'	System	12 Oct 2020 11:48:26

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:13', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3bf20201-c317-4d30-b481-dd78e1483204' User entered 'No (N)'	System	12 Oct 2020 11:48:26
	System	12 Oct 2020 11:48:26

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3bf20201-c317-4d30-b481-dd78e1483204'	System	12 Oct 2020 11:48:26
User entered 'No (N)'	System	12 Oct 2020 11:48:26

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:20', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3bf20201-c317-4d30-b481-dd78e1483204'	System	12 Oct 2020 11:48:26
User entered 'None (1)'	System	12 Oct 2020 11:48:26

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:23', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3bf20201-c317-4d30-b481-dd78e1483204'	System	12 Oct 2020 11:48:26
User entered '12 Oct 2020 06:48'	System	12 Oct 2020 11:48:26

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 6'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1037cb9a-1aa9-406f-b2ce-ed9703530caa' User entered 'None (1)'	System	13 Oct 2020 02:11:03
	System	13 Oct 2020 02:11:03

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:50', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1037cb9a-1aa9-406f-b2ce-ed9703530caa' User entered 'No (N)'	System	13 Oct 2020 02:11:03
	System	13 Oct 2020 02:11:03

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:53', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1037cb9a-1aa9-406f-b2ce-ed9703530caa' User entered 'No (N)'	System	13 Oct 2020 02:11:03
	System	13 Oct 2020 02:11:03

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:10:57', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1037cb9a-1aa9-406f-b2ce-ed9703530caa' User entered 'None (1)'	System	13 Oct 2020 02:11:03
	System	13 Oct 2020 02:11:03

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '1037cb9a-1aa9-406f-b2ce-ed9703530caa' User entered '12 Oct 2020 21:11'	System	13 Oct 2020 02:11:03
	System	13 Oct 2020 02:11:03

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 7'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:36', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '716c6eef-9227-45fb-a53c-d761b8c5ec9f' User entered 'None (1)'	System	13 Oct 2020 23:39:55
	System	13 Oct 2020 23:39:55

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:40', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '716c6eef-9227-45fb-a53c-d761b8c5ec9f' User entered 'No (N)'	System	13 Oct 2020 23:39:55
	System	13 Oct 2020 23:39:55

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '716c6eef-9227-45fb-a53c-d761b8c5ec9f' User entered 'No (N)'	System	13 Oct 2020 23:39:55
	System	13 Oct 2020 23:39:55

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '716c6eef-9227-45fb-a53c-d761b8c5ec9f' User entered 'None (1)'	System	13 Oct 2020 23:39:55
	System	13 Oct 2020 23:39:55

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:50', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '716c6eef-9227-45fb-a53c-d761b8c5ec9f' User entered '13 Oct 2020 18:39'	System	13 Oct 2020 23:39:55
	System	13 Oct 2020 23:39:55

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 13:10'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 15:40'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:42', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'No interference with activity (1)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:47', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'None (0)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:51', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'None (0)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:54', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'None (0)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:13:58', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'None (0)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:14:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'None (0)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:14:04', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered 'No (N)'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-07T23:14:09', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '7f09441a-a850-4d29-affa-5f315fd0fe45'	System	08 Oct 2020 04:14:13
User entered '07 Oct 2020 23:14'	System	08 Oct 2020 04:14:13

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '07 Oct 2020 16:35'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 2'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:09', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered 'None (0)'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:13', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb'	System	08 Oct 2020 23:50:03
User entered 'No interference with activity (1)'	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered 'No interference with activity (1)'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:23', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered 'None (0)'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered 'None (0)'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered 'None (0)'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:49:52', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered 'Yes (Y)'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-08T18:50:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '4d577a95-ccce-4662-9740-a49fd887defb' User entered '08 Oct 2020 18:50'	System	08 Oct 2020 23:50:03
	System	08 Oct 2020 23:50:03

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 3'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:08', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'None (0)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:10', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'None (0)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'None (0)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'None (0)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:21', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'None (0)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'None (0)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered 'No (N)'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-09T21:16:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '486f12c0-6fc0-46e0-a1d0-14e57d852d2c' User entered '09 Oct 2020 21:16'	System	10 Oct 2020 02:16:33
	System	10 Oct 2020 02:16:33

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 4'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'None (0)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'None (0)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:33', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'None (0)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:39', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'No interference with activity (1)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:42', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'None (0)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:45', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'None (0)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:48', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered 'No (N)'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-10T12:07:51', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '911fa007-835e-4e2f-823e-0b43e185314b' User entered '10 Oct 2020 12:07'	System	10 Oct 2020 17:07:53
	System	10 Oct 2020 17:07:53

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 5'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'None (0)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:31', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'None (0)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:34', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'None (0)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:38', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'None (0)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:40', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'None (0)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:43', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'None (0)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered 'No (N)'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T06:48:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '17c553f2-1aeb-4de7-8870-3898a67be4a8' User entered '12 Oct 2020 06:48'	System	12 Oct 2020 11:48:52
	System	12 Oct 2020 11:48:52

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 6'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:05', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'None (0)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:08', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'None (0)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'None (0)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'None (0)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:16', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'None (0)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'None (0)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:22', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered 'No (N)'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-12T21:11:25', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ab4d6df6-54ce-428a-a3d1-d361409a8643' User entered '12 Oct 2020 21:11'	System	13 Oct 2020 02:11:27
	System	13 Oct 2020 02:11:27

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	07 Oct 2020 17:53:07
User entered 'Day 7'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:55', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered 'None (0)'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:39:58', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered 'None (0)'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:40:01', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered 'None (0)'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:40:03', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered 'None (0)'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:40:06', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered 'None (0)'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:40:08', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered 'None (0)'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:40:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753'	System	13 Oct 2020 23:40:18
User entered 'No (N)'	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-10-13T18:40:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '3320fb38-9e11-470d-b4ed-d3ef1f745753' User entered '13 Oct 2020 18:40'	System	13 Oct 2020 23:40:18
	System	13 Oct 2020 23:40:18

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 17:53:07

US3492107

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 10 Jun 2021 07:59:21

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 17:53:07

US3492107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Gizelle Alvarez (b) (4)	15 Oct 2020 15:14:39

US3492107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '14 Oct 2020'	Gizelle Alvarez (b) (4)	15 Oct 2020 15:14:39

US3492107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	Gizelle Alvarez (b) (4)	15 Oct 2020 15:14:39

US3492107

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Gizelle Alvarez (b) (4)	15 Oct 2020 15:14:39

US3492107

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4)	15 Oct 2020 15:15:18

US3492107

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	15 Oct 2020 15:15:18

US3492107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	22 Oct 2020 13:55:38

US3492107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '21 Oct 2020'	(b) (4) Lorna Sanchez McCann	22 Oct 2020 13:55:38
	(b) (4)	

US3492107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Lorna Sanchez McCann (b) (4)	22 Oct 2020 13:55:38

US3492107

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Lorna Sanchez McCann (b) (4)	22 Oct 2020 13:55:38

US3492107

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Lorna Sanchez McCann	22 Oct 2020 13:55:43
	(b) (4)	

US3492107

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	22 Oct 2020 13:55:43

US3492107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:06:23

US3492107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '28 Oct 2020'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:06:23

US3492107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:06:23

US3492107

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:06:23

US3492107

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Oct 2020 21:06:39

US3492107

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	29 Oct 2020 21:06:39

US3492107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:50:29

US3492107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:50:29

US3492107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:50:29

US3492107

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'VISIT3'	System	04 Nov 2020 16:50:29

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '10:30'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '4 Nov 2020 10:30'	System	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '96.9' F	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Tympanic'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '85'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'bpm'	System	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'breaths/min'	System	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '129'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '77'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'mmHg'	System	04 Nov 2020 16:51:22

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13

US3492107

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13

US3492107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:28

US3492107

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:28

US3492107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:40

US3492107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '4 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:40

US3492107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '10:40'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:40

US3492107

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered '4 Nov 2020 10:40'	System	04 Nov 2020 16:51:40

US3492107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 16:51:44

US3492107

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	04 Nov 2020 16:51:44

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 64'	System	09 Sep 2020 18:18:09

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-11T12:41:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '9b51518e-a966-4f35-9021-ccaaeb230640' User entered 'No (N)'	System	11 Nov 2020 18:41:42
	System	11 Nov 2020 18:41:42

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-11T12:41:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '9b51518e-a966-4f35-9021-ccaaeb230640' User entered 'No (N)'	System	11 Nov 2020 18:41:42
	System	11 Nov 2020 18:41:42

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-11T12:41:38', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '9b51518e-a966-4f35-9021-ccaaeb230640' User entered '11 Nov 2020 12:41:38'	System	11 Nov 2020 18:41:42
	System	11 Nov 2020 18:41:42

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered '09 Nov 2020 00:01'	System	09 Sep 2020 18:18:09

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered '13 Nov 2020 23:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered 'Day 71'	System	09 Sep 2020 18:18:09

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-16T09:20:10', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa101e67-699a-4bbd-81f2-9ca3a3cffd88'	System	16 Nov 2020 15:20:49
User entered 'No (N)'	System	16 Nov 2020 15:20:49

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-16T09:20:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa101e67-699a-4bbd-81f2-9ca3a3cffd88'	System	16 Nov 2020 15:20:49
User entered 'Yes (Y)'	System	16 Nov 2020 15:20:49

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Please 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)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-16T09:20:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa101e67-699a-4bbd-81f2-9ca3a3cffd88'	System	16 Nov 2020 15:20:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	16 Nov 2020 15:20:49

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-16T09:20:38', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'aa101e67-699a-4bbd-81f2-9ca3a3cffd88' User entered '16 Nov 2020 09:20:38'	System	16 Nov 2020 15:20:49
	System	16 Nov 2020 15:20:49

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered '16 Nov 2020 00:01'	System	09 Sep 2020 18:18:09

US3492107

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:29:09
Data entry locked.	System	09 Sep 2020 18:18:09
User entered '20 Nov 2020 23:59'	System	09 Sep 2020 18:18:09

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-23T07:09:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f39b33f4-0779-404e-b208-2e004080c7b0' User entered 'No (N)'	System	23 Nov 2020 13:09:41
	System	23 Nov 2020 13:09:41

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-23T07:09:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f39b33f4-0779-404e-b208-2e004080c7b0'	System	23 Nov 2020 13:09:41
User entered 'No (N)'	System	23 Nov 2020 13:09:41

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-23T07:09:39', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f39b33f4-0779-404e-b208-2e004080c7b0'	System	23 Nov 2020 13:09:41
User entered '23 Nov 2020 07:09:39'	System	23 Nov 2020 13:09:41

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '20 Nov 2020 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '24 Nov 2020 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:04:12
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'AE already exists. This visit was for ongoing care.' (Site from DM).	Nia Moragne-O'Neal (b) (4)	11 Mar 2021 16:25:28
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 10:03:05
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-27T17:16:35', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6655f97e-3a47-41f5-9a51-7556f488cd95'	System	27 Nov 2020 23:17:40
User entered 'Yes (Y)'	System	27 Nov 2020 23:17:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-27T17:16:41', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6655f97e-3a47-41f5-9a51-7556f488cd95' User entered 'No (N)'	System	27 Nov 2020 23:17:40
	System	27 Nov 2020 23:17:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-27T17:16:48', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6655f97e-3a47-41f5-9a51-7556f488cd95'	System	27 Nov 2020 23:17:40
User entered 'No (N)'	System	27 Nov 2020 23:17:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-27T17:17:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6655f97e-3a47-41f5-9a51-7556f488cd95'	System	27 Nov 2020 23:17:40
User entered 'Yes (Y)'	System	27 Nov 2020 23:17:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-27T17:17:19', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6655f97e-3a47-41f5-9a51-7556f488cd95'	System	27 Nov 2020 23:17:40
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Nov 2020 23:17:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-11-27T17:17:29', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '6655f97e-3a47-41f5-9a51-7556f488cd95'	System	27 Nov 2020 23:17:40
User entered '27 Nov 2020 17:17:29'	System	27 Nov 2020 23:17:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '27 Nov 2020 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Dec 2020 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-04T08:43:45', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '12b62638-f09c-4042-b004-ab7fed799ef8'	System	04 Dec 2020 14:43:55
User entered 'No (N)'	System	04 Dec 2020 14:43:55

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-04T08:43:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '12b62638-f09c-4042-b004-ab7fed799ef8'	System	04 Dec 2020 14:43:55
User entered 'No (N)'	System	04 Dec 2020 14:43:55

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-04T08:43:53', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '12b62638-f09c-4042-b004-ab7fed799ef8' User entered '04 Dec 2020 08:43:53'	System	04 Dec 2020 14:43:55
	System	04 Dec 2020 14:43:55

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Dec 2020 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Dec 2020 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-12T02:13:12', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b5da017a-4e1b-4d21-9f59-954bf267568e' User entered 'No (N)'	System	12 Dec 2020 08:13:34
	System	12 Dec 2020 08:13:34

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-12T02:13:26', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b5da017a-4e1b-4d21-9f59-954bf267568e' User entered 'No (N)'	System	12 Dec 2020 08:13:34
	System	12 Dec 2020 08:13:34

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-12T02:13:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b5da017a-4e1b-4d21-9f59-954bf267568e' User entered '12 Dec 2020 02:13:32'	System	12 Dec 2020 08:13:34
	System	12 Dec 2020 08:13:34

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Dec 2020 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Dec 2020 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-18T02:55:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'cf38e2cd-1974-4eff-b906-ca75021ec339'	System	18 Dec 2020 08:55:50
User entered 'No (N)'	System	18 Dec 2020 08:55:50

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-18T02:55:38', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'cf38e2cd-1974-4eff-b906-ca75021ec339'	System	18 Dec 2020 08:55:50
User entered 'No (N)'	System	18 Dec 2020 08:55:50

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-18T02:55:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'cf38e2cd-1974-4eff-b906-ca75021ec339' User entered '18 Dec 2020 02:55:46'	System	18 Dec 2020 08:55:50
	System	18 Dec 2020 08:55:50

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 Dec 2020 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Dec 2020 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-25T08:19:57', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b21d4c40-fb6a-4a3c-a531-f2a6f662dcfb' User entered 'No (N)'	System	25 Dec 2020 14:20:35
	System	25 Dec 2020 14:20:35

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-25T08:20:03', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b21d4c40-fb6a-4a3c-a531-f2a6f662dcfb' User entered 'No (N)'	System	25 Dec 2020 14:20:35
	System	25 Dec 2020 14:20:35

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2020-12-25T08:20:31', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b21d4c40-fb6a-4a3c-a531-f2a6f662dcfb' User entered '25 Dec 2020 08:20:31'	System	25 Dec 2020 14:20:35
	System	25 Dec 2020 14:20:35

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 Dec 2020 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Dec 2020 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-01T09:54:24', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '9776d96b-58ff-4a53-8330-f7d57f90978e'	System	01 Jan 2021 15:54:49
User entered 'No (N)'	System	01 Jan 2021 15:54:49

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-01T09:54:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '9776d96b-58ff-4a53-8330-f7d57f90978e'	System	01 Jan 2021 15:54:49
User entered 'No (N)'	System	01 Jan 2021 15:54:49

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-01T09:54:46', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '9776d96b-58ff-4a53-8330-f7d57f90978e' User entered '01 Jan 2021 09:54:46'	System	01 Jan 2021 15:54:49
	System	01 Jan 2021 15:54:49

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Jan 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Jan 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-08T06:01:45', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '500b19a5-89b4-4367-ab21-b26cfab49604'	System	08 Jan 2021 12:02:14
User entered 'No (N)'	System	08 Jan 2021 12:02:14

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-08T06:01:56', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '500b19a5-89b4-4367-ab21-b26cfab49604'	System	08 Jan 2021 12:02:14
User entered 'No (N)'	System	08 Jan 2021 12:02:14

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-08T06:02:11', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '500b19a5-89b4-4367-ab21-b26cfab49604' User entered '08 Jan 2021 06:02:11'	System	08 Jan 2021 12:02:14
	System	08 Jan 2021 12:02:14

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Jan 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Jan 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-15T06:05:02', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b049e49c-43fd-4854-9960-756e8eb5718b'	System	15 Jan 2021 12:05:44
User entered 'Yes (Y)'	System	15 Jan 2021 12:05:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-15T06:05:08', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b049e49c-43fd-4854-9960-756e8eb5718b'	System	15 Jan 2021 12:05:44
User entered 'No (N)'	System	15 Jan 2021 12:05:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-15T06:05:14', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b049e49c-43fd-4854-9960-756e8eb5718b'	System	15 Jan 2021 12:05:44
User entered 'No (N)'	System	15 Jan 2021 12:05:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-15T06:05:20', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b049e49c-43fd-4854-9960-756e8eb5718b'	System	15 Jan 2021 12:05:44
User entered 'Yes (Y)'	System	15 Jan 2021 12:05:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-15T06:05:28', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b049e49c-43fd-4854-9960-756e8eb5718b'	System	15 Jan 2021 12:05:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 12:05:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-15T06:05:34', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b049e49c-43fd-4854-9960-756e8eb5718b' User entered '15 Jan 2021 06:05:34'	System	15 Jan 2021 12:05:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Jan 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Jan 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-22T09:59:21', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5bcde261-7554-4218-80d0-bd9b9905d3d0'	System	22 Jan 2021 16:00:17
User entered 'Yes (Y)'	System	22 Jan 2021 16:00:17

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-22T09:59:27', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5bcde261-7554-4218-80d0-bd9b9905d3d0'	System	22 Jan 2021 16:00:17
User entered 'No (N)'	System	22 Jan 2021 16:00:17

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-22T09:59:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5bcde261-7554-4218-80d0-bd9b9905d3d0'	System	22 Jan 2021 16:00:17
User entered 'No (N)'	System	22 Jan 2021 16:00:17

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-22T09:59:37', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5bcde261-7554-4218-80d0-bd9b9905d3d0'	System	22 Jan 2021 16:00:17
User entered 'Yes (Y)'	System	22 Jan 2021 16:00:17

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-22T09:59:48', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5bcde261-7554-4218-80d0-bd9b9905d3d0'	System	22 Jan 2021 16:00:17
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Jan 2021 16:00:17

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-22T09:59:56', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5bcde261-7554-4218-80d0-bd9b9905d3d0'	System	22 Jan 2021 16:00:17
User entered '22 Jan 2021 09:59:56'	System	22 Jan 2021 16:00:17

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Jan 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Jan 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-29T10:23:32', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08dd1691-a9fe-4d1e-b384-d5989a2215d1' User entered 'No (N)'	System	29 Jan 2021 16:23:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-29T10:23:36', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08dd1691-a9fe-4d1e-b384-d5989a2215d1' User entered 'No (N)'	System	29 Jan 2021 16:23:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-01-29T10:23:40', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '08dd1691-a9fe-4d1e-b384-d5989a2215d1' User entered '29 Jan 2021 10:23:40'	System	29 Jan 2021 16:23:44
	System	29 Jan 2021 16:23:44

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Jan 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Feb 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-08T18:29:21', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'e15e5fef-d712-40e2-b966-2a970fea9b83'	System	09 Feb 2021 00:30:02
User entered 'Yes (Y)'	System	09 Feb 2021 00:30:02

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-08T18:29:25', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'e15e5fef-d712-40e2-b966-2a970fea9b83'	System	09 Feb 2021 00:30:02
User entered 'No (N)'	System	09 Feb 2021 00:30:02

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-08T18:29:30', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'e15e5fef-d712-40e2-b966-2a970fea9b83'	System	09 Feb 2021 00:30:02
User entered 'No (N)'	System	09 Feb 2021 00:30:02

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-08T18:29:36', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'e15e5fef-d712-40e2-b966-2a970fea9b83'	System	09 Feb 2021 00:30:02
User entered 'Yes (Y)'	System	09 Feb 2021 00:30:02

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-08T18:29:45', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'e15e5fef-d712-40e2-b966-2a970fea9b83'	System	09 Feb 2021 00:30:02
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	09 Feb 2021 00:30:02

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-08T18:29:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'e15e5fef-d712-40e2-b966-2a970fea9b83'	System	09 Feb 2021 00:30:02
User entered '08 Feb 2021 18:29:49'	System	09 Feb 2021 00:30:02

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Feb 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Feb 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Feb 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Feb 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-19T08:40:49', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5dadcc99-d71b-44a5-bb3a-0f0bdf5802fe' User entered 'No (N)'	System	19 Feb 2021 14:41:04

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-19T08:40:53', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5dadcc99-d71b-44a5-bb3a-0f0bdf5802fe' User entered 'No (N)'	System	19 Feb 2021 14:41:04

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-02-19T08:41:02', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5dadcc99-d71b-44a5-bb3a-0f0bdf5802fe' User entered '19 Feb 2021 08:41:02'	System	19 Feb 2021 14:41:04
	System	19 Feb 2021 14:41:04

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Feb 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Feb 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-01T19:09:29-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'a52c3b94-7574-4cd1-b974-46556382e16b'	System	02 Mar 2021 01:09:40
User entered 'No (N)'	System	02 Mar 2021 01:09:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-01T19:09:32-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'a52c3b94-7574-4cd1-b974-46556382e16b'	System	02 Mar 2021 01:09:40
User entered 'No (N)'	System	02 Mar 2021 01:09:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-01T19:09:37-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'a52c3b94-7574-4cd1-b974-46556382e16b'	System	02 Mar 2021 01:09:40
User entered '01 Mar 2021 19:09:37'	System	02 Mar 2021 01:09:40

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Feb 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Mar 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-05T10:25:44-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ed347ef3-0913-47bc-87a4-1e984aab97dc'	System	05 Mar 2021 16:25:59
User entered 'No (N)'	System	05 Mar 2021 16:25:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-05T10:25:48-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ed347ef3-0913-47bc-87a4-1e984aab97dc' User entered 'No (N)'	System	05 Mar 2021 16:25:59
	System	05 Mar 2021 16:25:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-05T10:25:52-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ed347ef3-0913-47bc-87a4-1e984aab97dc' User entered '05 Mar 2021 10:25:52'	System	05 Mar 2021 16:25:59
	System	05 Mar 2021 16:25:59

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Mar 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Mar 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-13T10:37:10-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f3437ff4-46df-4ff9-bb2d-5f612cbba217'	System	13 Mar 2021 16:37:26
User entered 'No (N)'	System	13 Mar 2021 16:37:26

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-13T10:37:16-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f3437ff4-46df-4ff9-bb2d-5f612cbba217'	System	13 Mar 2021 16:37:26
User entered 'No (N)'	System	13 Mar 2021 16:37:26

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-13T10:37:24-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'f3437ff4-46df-4ff9-bb2d-5f612cbba217'	System	13 Mar 2021 16:37:26
User entered '13 Mar 2021 10:37:24'	System	13 Mar 2021 16:37:26

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Mar 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Mar 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-22T18:20:51-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'd49aa413-cef3-4a8c-89b8-7fbe4886a04f' User entered 'No (N)'	System	22 Mar 2021 23:21:03
	System	22 Mar 2021 23:21:03

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-22T18:20:55-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'd49aa413-cef3-4a8c-89b8-7fbe4886a04f' User entered 'No (N)'	System	22 Mar 2021 23:21:03

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-22T18:20:59-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'd49aa413-cef3-4a8c-89b8-7fbe4886a04f' User entered '22 Mar 2021 18:20:59'	System	22 Mar 2021 23:21:03
	System	22 Mar 2021 23:21:03

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Mar 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Mar 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-26T08:09:02-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '71a8a4d0-4836-4f6e-b9ab-f56b009a3127'	System	26 Mar 2021 13:09:22
User entered 'No (N)'	System	26 Mar 2021 13:09:22

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-26T08:09:09-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '71a8a4d0-4836-4f6e-b9ab-f56b009a3127'	System	26 Mar 2021 13:09:22
User entered 'No (N)'	System	26 Mar 2021 13:09:22

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-26T08:09:18-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '71a8a4d0-4836-4f6e-b9ab-f56b009a3127'	System	26 Mar 2021 13:09:22
User entered '26 Mar 2021 08:09:18'	System	26 Mar 2021 13:09:22

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Mar 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '30 Mar 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-02T07:11:49-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '118da2f6-f5cb-4380-b7b6-31bcc07e6191'	System	02 Apr 2021 12:12:11
User entered 'No (N)'	System	02 Apr 2021 12:12:11

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-02T07:11:56-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '118da2f6-f5cb-4380-b7b6-31bcc07e6191'	System	02 Apr 2021 12:12:11
User entered 'No (N)'	System	02 Apr 2021 12:12:11

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-02T07:12:08-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '118da2f6-f5cb-4380-b7b6-31bcc07e6191'	System	02 Apr 2021 12:12:11
User entered '02 Apr 2021 07:12:08'	System	02 Apr 2021 12:12:11

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Apr 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '06 Apr 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-09T18:41:27-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '41a62ff1-65d9-438e-aa31-c33f05b40adb' User entered 'No (N)'	System	09 Apr 2021 23:41:39

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-09T18:41:31-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '41a62ff1-65d9-438e-aa31-c33f05b40adb' User entered 'No (N)'	System	09 Apr 2021 23:41:39

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-09T18:41:37-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '41a62ff1-65d9-438e-aa31-c33f05b40adb' User entered '09 Apr 2021 18:41:37'	System	09 Apr 2021 23:41:39
	System	09 Apr 2021 23:41:39

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Apr 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '13 Apr 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-16T21:18:17-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c56385a8-0d95-4641-888b-86a0072c9e1b'	System	17 Apr 2021 02:18:29
User entered 'No (N)'	System	17 Apr 2021 02:18:29

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-16T21:18:21-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c56385a8-0d95-4641-888b-86a0072c9e1b'	System	17 Apr 2021 02:18:29
User entered 'No (N)'	System	17 Apr 2021 02:18:29

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-16T21:18:27-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'c56385a8-0d95-4641-888b-86a0072c9e1b'	System	17 Apr 2021 02:18:29
User entered '16 Apr 2021 21:18:27'	System	17 Apr 2021 02:18:29

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Apr 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '20 Apr 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-24T06:50:30-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ebabcce0-0766-412f-88f4-ae20f27df7fe' User entered 'No (N)'	System	24 Apr 2021 11:50:43

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-24T06:50:35-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ebabcce0-0766-412f-88f4-ae20f27df7fe' User entered 'No (N)'	System	24 Apr 2021 11:50:43

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-24T06:50:42-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'ebabcce0-0766-412f-88f4-ae20f27df7fe' User entered '24 Apr 2021 06:50:42'	System	24 Apr 2021 11:50:43
	System	24 Apr 2021 11:50:43

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Apr 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '27 Apr 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-30T17:58:14-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b058d542-107f-4d0e-921c-db60de0bc6b6'	System	30 Apr 2021 22:58:25
User entered 'No (N)'	System	30 Apr 2021 22:58:25

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Have you been exposed to someone with 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 (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-30T17:58:17-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b058d542-107f-4d0e-921c-db60de0bc6b6'	System	30 Apr 2021 22:58:25
User entered 'No (N)'	System	30 Apr 2021 22:58:25

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-04-30T17:58:22-05:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: 'b058d542-107f-4d0e-921c-db60de0bc6b6'	System	30 Apr 2021 22:58:25
User entered '30 Apr 2021 17:58:22'	System	30 Apr 2021 22:58:25

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '30 Apr 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 May 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '07 May 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 May 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '14 May 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 May 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '21 May 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 May 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '28 May 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Jun 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Jun 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Jun 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Jun 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Jun 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 Jun 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Jun 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 Jun 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Jun 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Jul 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '06 Jul 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Jul 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '13 Jul 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Jul 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '20 Jul 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Jul 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '27 Jul 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '30 Jul 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '03 Aug 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '06 Aug 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '10 Aug 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '13 Aug 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '17 Aug 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '20 Aug 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '24 Aug 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '27 Aug 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '31 Aug 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '03 Sep 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '07 Sep 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '10 Sep 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '14 Sep 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '17 Sep 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '21 Sep 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '24 Sep 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '28 Sep 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Oct 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Oct 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Oct 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Oct 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Oct 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Oct 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Oct 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Oct 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Oct 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Nov 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Nov 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Nov 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Nov 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Nov 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Nov 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Nov 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Nov 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '30 Nov 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '03 Dec 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '07 Dec 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '10 Dec 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '14 Dec 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '17 Dec 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '21 Dec 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '24 Dec 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '28 Dec 2021 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '31 Dec 2021 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Jan 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '07 Jan 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Jan 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '14 Jan 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 Jan 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '21 Jan 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 Jan 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '28 Jan 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Feb 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Feb 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Feb 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Feb 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Feb 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 Feb 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Feb 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 Feb 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Mar 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Mar 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Mar 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Mar 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Mar 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 Mar 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Mar 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 Mar 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Mar 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Apr 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Apr 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Apr 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Apr 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Apr 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Apr 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Apr 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Apr 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Apr 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '03 May 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '06 May 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '10 May 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '13 May 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '17 May 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '20 May 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '24 May 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '27 May 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '31 May 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '03 Jun 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '07 Jun 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '10 Jun 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '14 Jun 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '17 Jun 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '21 Jun 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '24 Jun 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '28 Jun 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Jul 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Jul 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Jul 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Jul 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Jul 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Jul 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '22 Jul 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Jul 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '29 Jul 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Aug 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '05 Aug 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Aug 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '12 Aug 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Aug 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '19 Aug 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Aug 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '26 Aug 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '30 Aug 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '02 Sep 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '06 Sep 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '09 Sep 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '13 Sep 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '16 Sep 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '20 Sep 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '23 Sep 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '27 Sep 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '30 Sep 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Oct 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '07 Oct 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Oct 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '14 Oct 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '18 Oct 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '21 Oct 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '25 Oct 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '28 Oct 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '01 Nov 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '04 Nov 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '08 Nov 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '11 Nov 2022 00:01'	System	20 Nov 2020 06:41:30

US3492107

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:59:21

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:41:30
Amendment Manager: User entered '15 Nov 2022 23:59'	System	20 Nov 2020 06:41:30

US3492107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:59:21

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:15:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-01T19:09:43-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5ecf2bee-6b7c-4e52-9c39-d05d09284967'	System	05 Mar 2021 16:25:44
User entered 'No (N)'	System	05 Mar 2021 16:25:44

US3492107

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:59:21

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:15:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (92F0E09C-9B13-468F-A5F9-055E5B449EF9)', Time: '2021-03-01T19:09:49-06:00', User OID: 'PatientReportedOutcome (US3492107)', ODM File OID: '5ecf2bee-6b7c-4e52-9c39-d05d09284967'	System	05 Mar 2021 16:25:44
User entered '01 Mar 2021 19:09:49'	System	05 Mar 2021 16:25:44

US3492107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:01

US3492107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '1 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:01

US3492107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:01

US3492107

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:01

US3492107

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Dec 2020 19:24:15

US3492107

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:52:13
User entered 'I'	System	01 Dec 2020 19:24:15

US3492107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	07 Jan 2021 15:26:18

US3492107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '7 Jan 2021'	Nia Moragne-O'Neal (b) (4)	07 Jan 2021 15:26:18

US3492107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	07 Jan 2021 15:26:18

US3492107

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	Nia Moragne-O'Neal (b) (4)	07 Jan 2021 15:26:18

US3492107

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	07 Jan 2021 15:26:25

US3492107

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User entered 'I'	System	07 Jan 2021 15:26:25

US3492107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:02:51

US3492107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:02:51

US3492107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:02:51

US3492107

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:02:51

US3492107

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Feb 2021 20:02:58

US3492107

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User entered 'I'	System	04 Feb 2021 20:02:58

US3492107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:19:32

US3492107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered '3 Mar 2021'	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:19:32

US3492107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:19:32

US3492107

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 07:59:21

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered empty.	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:19:32

US3492107

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:19:35

US3492107

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:31:46
User entered 'I'	System	03 Mar 2021 15:19:35

US3492107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:36:54

US3492107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:36:54

US3492107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:36:54

US3492107

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	08 Apr 2021 16:36:54

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '10:28'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 10:28'	System	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '98.5' F	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Other (Other)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'tympanic'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '69'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '20'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '127'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '71'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 16:37:29

US3492107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:37

US3492107

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:37

US3492107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:51

US3492107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '08 Apr 2021'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:51

US3492107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '10:38'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:37:51

US3492107

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '08 Apr 2021 10:38'	System	08 Apr 2021 16:37:51

US3492107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:38:12

US3492107

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 07:59:21

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 16:38:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:21

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:45:04

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:21

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '15:00'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:45:04

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:21

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:49
User entered '12 Nov 2020 15:00'	System	12 Nov 2020 22:45:04

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:21

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:45:04

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID-19 Contact

Generated On: 10 Jun 2021 07:59:21

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:49
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:45:04

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Day 1 (Day 1)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '100'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User entered '%'	System	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '97.9' F	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (1)

Generated On: 10 Jun 2021 07:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:46:44

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Day 2 (Day 2)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '13 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '99'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User entered '%'	System	14 Nov 2020 22:25:35

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '97.6' F	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (2)

Generated On: 10 Jun 2021 07:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:25:35

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Day 3 (Day 3)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '14 Nov 2020'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '98'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User entered '%'	System	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '97.9' F	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Mild (Mild)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (3)

Generated On: 10 Jun 2021 07:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	14 Nov 2020 22:27:57

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Day 4 (Day 4)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '15 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '98'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User entered '%'	System	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '98.1' F	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Mild (Mild)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (4)

Generated On: 10 Jun 2021 07:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	Andrea Wendrow (b) (4)	15 Nov 2020 22:08:12

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '16 Nov 2020'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '99'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

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Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User entered '%'	System	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: Symptom Log (5)

Generated On: 10 Jun 2021 07:59:21

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:13:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	16 Nov 2020 20:32:05

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 12 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 07:14:43
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 12 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'corrected' (Site from DM).	Andrea Wendrow (b) (4)	28 Nov 2020 21:20:34
User entered '12 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:16:30
User entered '16 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:15:17
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 12 NOV 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same SARS-CoV-2 serum sample data is missing in EDC. Please review if the SARS-CoV-2 serum sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 05:57:01
User entered '12 Nov 2020'	(b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Per CDM: Previous query response states 'yes' when asked to confirm test result was positive, however response to 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' was updated to 'No'. Please review and clarify if the patient tested positive or not and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Jan 2021 11:18:20
Query 'Per CDM: Previous query response states 'yes' when asked to confirm test result was positive, however response to 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' was updated to 'No'. Please review and clarify if the patient tested positive or not and update as appropriate.' answered with 'it was negative.' (Site from DM).	Andrea Wendrow (b) (4) (b) (4)	23 Dec 2020 00:07:26
User opened query 'Per CDM: Previous query response states 'yes' when asked to confirm test result was positive, however response to 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR?' was updated to 'No'. Please review and clarify if the patient tested positive or not and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 11:46:15
User closed query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	(b) (4), (b) (6)	21 Dec 2020 11:44:37
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:16:30
Query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' answered with 'yes' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:15:45
User opened query 'Did Subject Test Positive For SARS-CoV-2 by RT-PCR is Yes. Please confirm test result was positive and enter COVID-19 diagnosis on the Adverse Events form.' (Site from System).	System	28 Nov 2020 21:15:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:15:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Nov 2020 21:28:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Nov 2020 21:28:01
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Nov 2020 21:28:01
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Nov 2020 22:47:02
User entered empty.	(b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4)	
User entered '16 Nov 2020' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:16:30
User entered '12 Nov 2020'	(b) (4)	28 Nov 2020 21:15:37
	(b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[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)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:47:02

US3492107

Folder: Covid-19 Assessment 12 Nov 2020

Form: COVID Diagnostic Test

Generated On: 10 Jun 2021 07:59:21

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 03:14:10
User entered '0'	System	28 Nov 2020 21:16:30
User entered '1'	System	28 Nov 2020 21:15:37
User entered '0'	System	19 Nov 2020 21:28:01

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:24:02

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Andrea Wendrow (b) (4) (b) (4)	28 Nov 2020 21:24:02

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

US3492107

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:59:21

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:59:21

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02

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Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:24:02
	(b) (4)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:19:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:19:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Home (Home)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:19:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User entered 'SICKD1'	System	28 Nov 2020 21:19:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '15:00'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User entered '12 Nov 2020 15:00'	System	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28
DataPoint set to visible.	(b) (4) System	28 Nov 2020 21:19:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered missing code ND - Not Done.	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28
DataPoint set to visible.	(b) (4) System	28 Nov 2020 21:19:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:26:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Nov 2020 21:26:14
User entered '97.9' F reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:26:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:21:28
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Oral (Oral)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered empty.	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:26:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Nov 2020 21:26:14
User entered '68' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:26:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:21:28
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User entered 'bpm'	System	28 Nov 2020 21:26:14
User entered empty.	System	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:26:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Nov 2020 21:26:14
User entered '16' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:26:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:21:28
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User entered 'breaths/min'	System	28 Nov 2020 21:26:14
User entered empty.	System	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:26:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Nov 2020 21:26:14
User entered '148' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:26:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:21:28
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User entered 'mmHg'	System	28 Nov 2020 21:26:14
User entered empty.	System	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:26:14
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	28 Nov 2020 21:26:14
User entered '78' reason for change: Data Entry Error	Andrea Wendrow (b) (4)	28 Nov 2020 21:26:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Nov 2020 21:21:28
User entered empty.	Andrea Wendrow (b) (4)	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User entered 'mmHg'	System	28 Nov 2020 21:26:14
User entered empty.	System	28 Nov 2020 21:21:28

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15

US3492107

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 07:59:21

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15

US3492107

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:21:40

US3492107

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 07:59:21

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020'	Andrea Wendrow (b) (4)	28 Nov 2020 21:21:40

US3492107

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 07:59:21

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:23:41

US3492107

Folder: Illness Visit Day 1 (1)

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

Generated On: 10 Jun 2021 07:59:21

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 17:44:15
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '12 Nov 2020'	(b) (4) Andrea Wendrow (b) (4)	28 Nov 2020 21:23:41

US3492107

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:14
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:32:49

US3492107

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:32:49

US3492107

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:14
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:32:49

US3492107

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

Form: Visit Date

Generated On: 10 Jun 2021 07:59:21

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'UNBLND_DECIDE'	System	07 Mar 2021 17:32:49

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	06 Mar 2021 18:58:14
Amendment Manager: User opened query 'Data is required. Please complete.' (Site from System).	System	27 Feb 2021 19:25:28
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
User closed query 'Per CDM: Per sponsor review, please complete Study Discontinuation CRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 16:02:29
Query 'Per CDM: Per sponsor review, please complete Study Discontinuation CRF. Thank you.' answered with 'please see ePIF #426326' (Site from DM).	Andrea Wendrow (b) (4)	09 Apr 2021 22:17:40
User opened query 'Per CDM: Per sponsor review, please complete Study Discontinuation CRF. Thank you.' (Site from DM).	(b) (4)	
User signature succeeded.	(b) (4), (b) (6)	07 Apr 2021 17:09:15
DataPoint Verified.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered 'I'	(b) (4)	
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	16 Mar 2021 16:45:20
	(b) (4)	
	Andrea Wendrow (b) (4)	07 Mar 2021 17:34:31
	(b) (4)	
	System	06 Mar 2021 18:58:15

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered 'Yes (Y)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	18 Feb 2021 16:49:09
Query 'Data is required. Please complete.' answered with 'not done yet' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	16 Feb 2021 16:25:40
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Feb 2021 15:41:42
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered 'Amendment 5 (Amendment 5)'	Andrea Wendrow (b) (4)	07 Mar 2021 17:34:31
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 18:58:15

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered '08 Jan 2021' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	07 Mar 2021 17:34:31
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Participant randomization assignment](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	07 Mar 2021 17:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Actual Dose 1](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	07 Mar 2021 17:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Actual Dose 2](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	07 Mar 2021 17:34:31
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:20
User entered 'No (N)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:31
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Placebo Only Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 15:41:42

US3492107

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

Form: Unblinding

Generated On: 10 Jun 2021 07:59:21

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Feb 2021 15:41:42

US3492107

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:24
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:44

US3492107

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:44

US3492107

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:24
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:44

US3492107

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

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 07:59:21

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Mar 2021 17:34:44

US3492107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:21

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:27
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:54

US3492107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:27
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:54

US3492107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:21

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 16:45:27
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	07 Mar 2021 17:34:54

US3492107

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 07:59:21

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Mar 2021 17:34:54

US3492107

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 07:59:21

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:28
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4)	08 Jan 2021 23:15:23
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:31:32

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Mar 2021 18:29:32
Reviewed for Safety.	(b) (4), (b) (6)	04 Mar 2021 18:02:56
User entered	System	11 Jan 2021 16:11:10
'USA-US101-2021-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	11 Jan 2021 16:11:10

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease aggravated - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 13:32:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	13 Apr 2021 13:32:58
	(b) (4)	
Data point term sent to Coder	System	12 Apr 2021 20:33:30
DataPoint Un-verified.	Diana Bahena (b) (4)	12 Apr 2021 20:33:04
	(b) (4)	
Coding entries removed.	Diana Bahena (b) (4)	12 Apr 2021 20:33:04
	(b) (4)	
User entered 'WORSENING OF EXISTING CORONARY ARTERY Disease' reason for change:	Diana Bahena (b) (4)	12 Apr 2021 20:33:04
	(b) (4)	
Data Entry Error		
User closed query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4), (b) (6)	30 Mar 2021 15:59:20
' (Site from DM).		
Query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	Andrea Wendrow (b) (4)	29 Mar 2021 19:39:17
	(b) (4)	
' answered with 'Coronary artery blockage has been in the medical history since Sep 2020' (Site from DM).		
User opened query 'Per DM CLR: Worsening AE is noted, but no baseline medical history or adverse event condition is found. Please confirm if this is a worsening; if yes, please add baseline Medical history or prior AE to the appropriate page as applicable.	(b) (4), (b) (6)	25 Mar 2021 05:29:45
' (Site from DM).		
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery occlusion, LLT: Coronary artery occlusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 21:21:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 21:21:00
Data point term sent to Coder	System	08 Jan 2021 23:48:27
User entered 'Worsening of existing coronary artery blockage'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '8 Jan 2021'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:18:18
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '11 Jan 2021' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:18:18
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:20:12
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:33:40
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:53:20
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Grade 4 (Grade 4)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 11:30:40
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'subject just admitted, outcome and d/c date and ICU information currently unknown' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:48:44
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	08 Jan 2021 23:47:31
User entered 'I'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (1)

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '8 Jan 2021'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Form: Adverse Events (1)

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Un-verified.	(b) (4)	
	Marla Schwarber (b) (4)	23 Apr 2021 17:49:22
	(b) (4)	
User entered '15 Jan 2021' reason for change: Per Query Resolution	Marla Schwarber (b) (4)	23 Apr 2021 17:49:22
	(b) (4)	
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)	30 Mar 2021 01:40:45
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:40:42
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 'We have requested multiple times, have yet to receive and subject is still to fragile to come into clinic for study visits.' (Site from Safety).	Andrea Wendrow (b) (4)	29 Mar 2021 19:42:07
	(b) (4)	
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'Because she is 75 years old and had a triple bypass open heart surgery procedure.' (Site from Safety).	Andrea Wendrow (b) (4)	29 Mar 2021 19:41:55
	(b) (4)	
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)	11 Mar 2021 21:38:46

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:36:35
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 14:20:15
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 19:33:35
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '23 Jan 2021' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:18:18
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:53:02
User entered empty.	Andrea Wendrow (b) (4)	(b) (4) 08 Jan 2021 23:47:31

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User closed query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	14 Jan 2021 11:30:37
Query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'subject just admitted, outcome and d/c date and ICU information currently unknown' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:48:51
User opened query 'Admitted to ICU?' is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	08 Jan 2021 23:47:31
User entered 'Unknown (UNK)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	12 Apr 2021 21:32:23
User entered '0' reason for change: Per Query Resolution	Diana Bahena (b) (4)	12 Apr 2021 21:32:23
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	12 Apr 2021 21:29:59
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 19:42:16
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	08 Mar 2021 19:35:34
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 19:35:34
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 19:35:34
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	03 Mar 2021 15:18:18
User entered '1' reason for change: New Information	Nia Moragne-O'Neal	03 Mar 2021 15:18:18
	(b) (4)	
User entered '0'	Andrea Wendrow (b) (4)	08 Jan 2021 23:47:31
	(b) (4)	

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Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
User entered '1' reason for change: Per Query Resolution	Diana Bahena (b) (4)	12 Apr 2021 22:01:38
	(b) (4)	
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of CAROTID ARTERY BLOCKAGE. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:25:28
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of CAROTID ARTERY BLOCKAGE. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:42:23
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 19:42:16
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 19:42:16
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, ConMed recorded was given prior to the start date of this worsening condition and appears to be used for the MH of CAROTID ARTERY BLOCKAGE. Please review and confirm if there are new medications used to treat this worsening condition. If yes, review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:26:54
User entered '1'	Andrea Wendrow (b) (4)	08 Jan 2021 23:47:31
	(b) (4)	

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Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User closed query 'PV Query: Updated Please provide the date of surgical procedure.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:29:03
Query 'PV Query: Updated Please provide the date of surgical procedure.' answered with 'updated' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:32:43
User entered '1' reason for change: Per Query Resolution	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:29:59
User opened query 'PV Query: Updated Please provide the date of surgical procedure.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:26:00
User closed query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 06:27:28
Query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:42:33
DataPoint Un-verified.	(b) (4), (b) (6)	08 Mar 2021 19:42:16
User entered '0' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 19:42:16
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User opened query 'Per DM CLR: Other Action Taken = Con Proc. However, ConProc indication is Medical History and not Adverse Event. Please review and verify if the CP indication should be updated so there will be an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 07:27:02
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	08 Jan 2021 23:47:31

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User closed query 'PV Query: Event is reported to be resolved with sequelae. Please provide the recurrent condition for this event.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:29:30
Query 'PV Query: Event is reported to be resolved with sequelae. Please provide the recurrent condition for this event.' answered with 'updated' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 22:07:20
User opened query 'PV Query: Event is reported to be resolved with sequelae. Please provide the recurrent condition for this event.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:33:12
User closed query 'PV Query: Event is reported to be resolved with sequelae. Please provide the recurrent condition for this event.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:40:53
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:40:50
Query 'PV Query: Event is reported to be resolved with sequelae. Please provide the recurrent condition for this event.' answered with 'pending' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	29 Mar 2021 19:51:54
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'pending' (Site from Safety).	Andrea Wendrow (b) (4) (b) (4)	29 Mar 2021 19:51:45
User opened query 'PV Query: Event is reported to be resolved with sequelae. Please provide the recurrent condition for this event.' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:37:03
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Nia Moragne-O'Neal (b) (4)	03 Mar 2021 15:18:18

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:53:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Andrea Wendrow (b) (4)	08 Jan 2021 23:47:31

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
User entered 'Required cardiac rehab post surgery' reason for change: Per Query Resolution	Diana Bahena (b) (4)	12 Apr 2021 22:07:13
	(b) (4)	
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	29 Mar 2021 19:52:19
DataPoint Un-verified.	Andrea Wendrow (b) (4)	29 Mar 2021 19:52:19
	(b) (4)	
User entered 'pending reports' reason for change: Per Query Resolution	Andrea Wendrow (b) (4)	29 Mar 2021 19:52:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	03 Mar 2021 15:18:18
User entered empty.	Andrea Wendrow (b) (4)	08 Jan 2021 23:47:31
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User closed query 'PV Query: Kindly confirm hospital discharge date. According to the medical records the subject was discharged on 15 Jan 2021.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:55:48
' (Site from Safety).		
User closed query 'PV Query: Please provide the results of the tests performed during the hospitalization (CT chest, US carotid duplex, portable CXR, CXR 2 view, Echo with doppler), if known. ' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 15:55:46
Query 'PV Query: Kindly confirm hospital discharge date. According to the medical records the subject was discharged on 15 Jan 2021.	Marla Schwarber (b) (4) (b) (4)	23 Apr 2021 17:51:39
' answered with 'Participant discharged from inpatient hospitalization on 15JAN2021 to subacute rehabilitation. Discharged from rehab 23JAN2021.' (Site from Safety).		
Query 'PV Query: Please provide the results of the tests performed during the hospitalization (CT chest, US carotid duplex, portable CXR, CXR 2 view, Echo with doppler), if known. ' answered with 'Records faxed' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	23 Apr 2021 17:42:31
User opened query 'PV Query: Kindly confirm hospital discharge date. According to the medical records the subject was discharged on 15 Jan 2021.	(b) (4), (b) (6)	23 Apr 2021 13:10:14
' (Site from Safety).		
User opened query 'PV Query: Please provide the results of the tests performed during the hospitalization (CT chest, US carotid duplex, portable CXR, CXR 2 view, Echo with doppler), if known. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 13:10:06
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)	13 Apr 2021 17:29:38

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:29:33
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 17:29:23
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 'faxed today @1738' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 22:43:55
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'faxed today @1738' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 22:43:52
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'updated with covid test and results' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:33:24
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:31:57

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT CALLED TO REPORT THAT WAS BEING ADMITTED TO HOSPITAL AFTER ANGIOGRAM SHOWING HIGH DEGREE OF BLOCKAGE IN 3 ARTERIES (90%, 85% AND 65% BUT WAS UNSURE WHICH ARTERIES AFFECTED). PER PI, SHOULD UNBLIND SUBJECT. PI REPORTED THAT SUBJECT HAD RECEIVED ACTIVE PRODUCT. SUBJECT (AND CARDIOLOGY STAFF WHO WAS PRESENT IN ROOM AT TIME OF CALL TO SUBJECT TO UNBLIND) WERE INFORMED. CURRENT STATUS IS UNKNOWN AND TYPE OF SURGERY PLANNED AND DATE ALSO UNKNOWN BUT SUBJECT WILL NOT BE DISCHARGED UNTIL AFTER SURGERY. />10Jan2021 - Covid test negative' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:31:57
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)	07 Apr 2021 14:38:09
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:19:27
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:18:24
User closed query 'PV Query: Please fill out unblinding eCRF page.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:41:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Was the subject experiencing any new symptoms, or was this finding part of routine monitoring? lease provide details' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:41:08
User closed query 'PV Query: Please confirm if any additional treatment will be provided for the event. If treatment medications were given, please add to the concomitant medication eCRF page.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:41:06
User closed query 'PV Query: Please provide the name and date of surgical procedure.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:41:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:40:59
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Mar 2021 01:40:56
Query 'PV Query: Please fill out unblinding eCRF page.' answered with 'done' (Site from Safety).	Andrea Wendrow (b) (4)	29 Mar 2021 19:51:32
Query 'PV Query: Was the subject experiencing any new symptoms, or was this finding part of routine monitoring? lease provide details' answered with 'routine' (Site from Safety).	Andrea Wendrow (b) (4)	29 Mar 2021 19:51:21
Query 'PV Query: Please confirm if any additional treatment will be provided for the event. If treatment medications were given, please add to the concomitant medication eCRF page.' answered with 'pending' (Site from Safety).	Andrea Wendrow (b) (4)	29 Mar 2021 19:51:01
Query 'PV Query: Please provide the name and date of surgical procedure.' answered with 'pending' (Site from Safety).	Andrea Wendrow (b) (4)	29 Mar 2021 19:50:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'pending' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 29 Mar 2021 19:50:49
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'pending' (Site from Safety).	Andrea Wendrow (b) (4)	(b) (4) 29 Mar 2021 19:50:43
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User opened query 'PV Query: Please fill out unblinding eCRF page.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:54:59
User opened query 'PV Query: Was the subject experiencing any new symptoms, or was this finding part of routine monitoring? lease provide details' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:54:35
User opened query 'PV Query: Please confirm if any additional treatment will be provided for the event. If treatment medications were given, please add to the concomitant medication eCRF page.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:54:23
User opened query 'PV Query: Please provide the name and date of surgical procedure.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:53:57
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:53:46
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	14 Jan 2021 14:53:40

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject called to report that was being admitted to hospital after angiogram showing high degree of blockage in 3 arteries (90%, 85% and 65% but was unsure which arteries affected). Per PI, should unblind subject. PI reported that subject had received active product. Subject (and cardiology staff who was present in room at time of call to subject to unblind) were informed. Current status is unknown and type of surgery planned and date also unknown but subject will not be discharged until after surgery.'	Andrea Wendrow (b) (4)	(b) (4) 08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Jan 2021 23:47:31

US3492107

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 07:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Jan 2021 23:47:31

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:36:14
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'PD created' (Site from DM).	Andrea Wendrow (b) (4)	13 Apr 2021 17:42:28
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 16:13:44
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 22:16:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	09 Feb 2021 22:16:40
Data point term sent to Coder	System	09 Feb 2021 21:36:43
Coding entries removed.	(b) (4), (b) (6)	09 Feb 2021 21:36:16
User entered 'Fever of Unknown Etiology' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 21:36:16

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 21:33:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Feb 2021 21:33:37
Data point term sent to Coder	System	09 Feb 2021 21:32:40
User entered 'Fever'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '5 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User closed query 'Start time is present for an AE that System did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).		10 Feb 2021 19:09:25
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4)	10 Feb 2021 19:09:25
	(b) (4)	
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	09 Feb 2021 21:32:25
User entered '20:00'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User entered empty.	System	10 Feb 2021 19:09:25
User entered '5 Feb 2021 20:00'	System	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '6 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
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	10 Feb 2021 19:09:25
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4)	10 Feb 2021 19:09:25
	(b) (4)	
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	09 Feb 2021 21:32:25
User entered '08:00'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User entered empty.	System	10 Feb 2021 19:09:25
User entered '6 Feb 2021 08:00'	System	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'None (NONE)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'l'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[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 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:32
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User entered '0'	System	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56
User entered '0'	System	09 Feb 2021 21:32:25

US3492107

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 07:59:21

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 09:49:56

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 07:59:21

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 18:17:14

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
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) (b) (4)	05 Nov 2020 21:30:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 21:30:28
Data point term sent to Coder	System	05 Nov 2020 15:34:14
Coding entries removed.	(b) (4), (b) (6)	05 Nov 2020 15:34:12
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) (b) (4)	10 Sep 2020 18:21:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:21:47
Data point term sent to Coder	System	10 Sep 2020 18:20:11
User entered 'atorvastatin'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:15:30
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'updated per medical history form, will make a note to ask about hld on next visit' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 15:34:44
User entered 'HYPERLIPIDEMIA/R carotid artery blockage' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Nov 2020 15:34:12
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:56:08
User entered 'hyperlipidemia'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '80'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'un UNK 2005'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:19:37

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:48:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:48:35
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:47:50 09 Nov 2020 19:47:41
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 07:22:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 07:22:45
Data point term sent to Coder User entered 'losartan'	System (b) (4), (b) (6)	10 Sep 2020 18:21:14 10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:15:35
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'updated med hx' (Site from DM).	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:48:30
User entered 'HYPERTENSION' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:47:41
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:56:19
User entered 'hypertension/kidney'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '100'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:20:20

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:51:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Nov 2020 19:51:36
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:50:53 09 Nov 2020 19:50:09
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:26:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:26:44
Data point term sent to Coder User entered 'levothyroxine'	System (b) (4), (b) (6)	10 Sep 2020 18:25:31 10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:15:40
User entered 'HYPOTHYROIDISM' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:50:09
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:49:10
' answered with 'updated' (Site from DM).		
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:56:33
User entered 'hypothyroid'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '75'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:11:35
Query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:16:13
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:16:07
User opened query 'Per CDM: MCG is equivalent to UG. Since UG is an option in the drop down, please consider updating Dose Unit to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 18:52:28
Data hard unlocked.	(b) (4), (b) (6)	15 Sep 2020 18:52:21
Data hard locked.	(b) (4), (b) (6)	15 Sep 2020 18:52:07
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:16:07
User entered 'mcg'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'un UNK 2000'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:25:05

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:28:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:28:45
Data point term sent to Coder	System	10 Sep 2020 18:27:33
User entered 'lantus'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'diabetes'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '30'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'not specified'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:27:25

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: EFLORNITHINE HYDROCHLORIDE, PRODUCTSYNONYM: VANIQA [EFLORNITHINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:05:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Nov 2020 06:05:39
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:50:53 09 Nov 2020 19:50:30
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: EFLORNITHINE HYDROCHLORIDE, PRODUCTSYNONYM: VANIQA [EFLORNITHINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:37:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 12:37:34
Data point term sent to Coder User entered 'vaniqa (eflornithine hydrochloride)'	System (b) (4), (b) (6)	10 Sep 2020 18:30:40 10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 17:16:01
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF.	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:52:05
' answered with 'updated' (Site from DM).		
User entered 'Facial Hair' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	09 Nov 2020 19:50:30
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 09:56:45
User entered 'hair on face'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'unk'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Other (OTHER)'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'not specified'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Topical (TOPICAL)'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:30:12

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
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)	10 Sep 2020 18:32:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 18:32:42
Data point term sent to Coder	System	10 Sep 2020 18:31:44
User entered 'alprazolam'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'anxiety'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0.5'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'mg (mg)'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'as needed (PRN)'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'un UNK 2010'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 18:31:08

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User closed query 'Per ETRTR, Please note that according to SAE Worsening of Existing Coronary Artery Blockage page, conmeds were administered but no conmeds related to this event is entered. Please reconcile.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:54
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:24:13
Query 'Per ETRTR, Please note that according to SAE Worsening of Existing Coronary Artery Blockage page, conmeds were administered but no conmeds related to this event is entered. Please reconcile.' answered with 'updated' (Site from CRA).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 22:00:29
User opened query 'Per ETRTR, Please note that according to SAE Worsening of Existing Coronary Artery Blockage page, conmeds were administered but no conmeds related to this event is entered. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 15:19:03
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) (b) (4)	29 Oct 2020 21:08:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	29 Oct 2020 21:08:44
Data point term sent to Coder	System	29 Oct 2020 21:08:12
User entered 'flu shot'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'vaccination'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0.5'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please review the dose unit as this is not the expected unit for this medication.. Please update dose unit to either volume administered (e.g. 0.5 ml) or dosage form (e.g.1 injection). Verify and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Jan 2021 11:04:18
Query 'Per DM CLR: Please review the dose unit as this is not the expected unit for this medication.. Please update dose unit to either volume administered (e.g. 0.5 ml) or dosage form (e.g.1 injection). Verify and update eCRF as appropriate. ' answered with '-----Corrected. Thank you.-----' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 20:13:23
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Jan 2021 20:13:04
User opened query 'Per DM CLR: Please review the dose unit as this is not the expected unit for this medication.. Please update dose unit to either volume administered (e.g. 0.5 ml) or dosage form (e.g.1 injection). Verify and update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 21:24:56
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '26 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '26 Oct 2020'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User entered empty.	System	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User entered empty.	System	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:14:04
User entered empty.	System	29 Oct 2020 21:08:03

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:42:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:42:41
Data point term sent to Coder Coding entries removed.	System Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:57:58 12 Apr 2021 21:57:55
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:21:05
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:21:05
Data point term sent to Coder User entered 'Furosemide'	System (b) (4), (b) (6)	05 Feb 2021 21:20:35 05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
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. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:24:57
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. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:58:00
User entered 'CAD' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:57:55
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. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:03:09
User entered 'Diuretic'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '20'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'other (OTHER)'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Every Morning PRN'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '30 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 21:20:17

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:25:30
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:13:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:13:52
Data point term sent to Coder	System	12 Apr 2021 21:58:58
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:58:43
Coding entries removed.	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:58:37
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:06:58
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:21:49

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	05 Feb 2021 21:21:49
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	05 Feb 2021 21:21:36
User entered 'Metoprolol'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Worsening CAD' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:58:37
User entered 'Hypertension'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '50'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'mg (mg)'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'twice daily (BID)'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '30 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:21:31

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: COLECALCIFEROL, PRODUCTSYNONYM: VITAMIN D 3 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:23:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 21:23:49
Data point term sent to Coder	System	05 Feb 2021 21:23:38
User entered 'Vitamin D 3'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:52:55
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	24 Mar 2021 20:26:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	24 Mar 2021 20:26:35
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:03:52
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Supplement'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '1,000'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'IU (IU)'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '30 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:22:42

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
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)	05 Feb 2021 21:25:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Feb 2021 21:25:49
	(b) (4)	
Data point term sent to Coder	System	05 Feb 2021 21:24:39
User entered 'MultiVitamin'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 06:53:01
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	24 Mar 2021 20:26:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	24 Mar 2021 20:26:01
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Mar 2021 09:03:38
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Supplement'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'I'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'once daily (QD)'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '30 Jan 2021'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Feb 2021 21:23:43

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
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)	09 Feb 2021 21:39:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 21:39:38
Data point term sent to Coder	System	09 Feb 2021 21:38:44
User entered 'Acetaminophen'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Fever'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '1,000'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'mg (mg)'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'as needed (PRN)'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '5 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:37:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:44:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 09:44:51
Data point term sent to Coder	System	12 Apr 2021 21:59:59
Coding entries removed.	Diana Bahena (b) (4) (b) (4)	12 Apr 2021 21:59:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 22:21:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Feb 2021 22:21:38
Data point term sent to Coder	System	09 Feb 2021 21:40:46
User entered 'Hydrocodone 5/325'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Review if this is related to Coronary artery blockage and if there is any surgical procedure done. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 18:26:08
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Review if this is related to Coronary artery blockage and if there is any surgical procedure done. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4)	12 Apr 2021 21:59:37
	(b) (4)	
User entered 's/p CABG (due to worsening CAD)' reason for change: Data Entry Error	Diana Bahena (b) (4)	12 Apr 2021 21:59:32
	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Review if this is related to Coronary artery blockage and if there is any surgical procedure done. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:53:06
User entered 'Post Cardiac Surgical Pain'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 16:24:13
User closed query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 22:36:17
Query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 19:44:58
User entered '1' reason for change: Per Query Resolution	(b) (4), (b) (6)	08 Mar 2021 19:44:51
User opened query 'Per DM CLR: Please provide the number of dose in numeric format. Update entry as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 06:53:23
User entered 'one'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'as needed (PRN)'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '30 Jan 2020'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered '0'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 16:24:13
User entered 'No (N)'	(b) (4), (b) (6)	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 07:59:21

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 21:39:51

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 07:59:21

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:14
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered 'Yes (Y)' reason for change: New Information	(b) (4) Andrea Wendrow (b) (4)	08 Jan 2021 23:38:15
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 18:31:50

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:21

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
	(b) (4)	
User entered '8 Jan 2021'	Andrea Wendrow (b) (4)	08 Jan 2021 23:38:54
	(b) (4)	

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
	(b) (4)	
User entered 'angiogram'	Andrea Wendrow (b) (4)	08 Jan 2021 23:38:54
	(b) (4)	

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
	(b) (4)	
User entered 'Medical History (MH)'	Andrea Wendrow (b) (4)	08 Jan 2021 23:38:54
	(b) (4)	

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 07:59:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:01
	(b) (4)	
User entered empty.	Andrea Wendrow (b) (4)	08 Jan 2021 23:38:54
	(b) (4)	

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:21

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:27
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '11 Jan 2021'	Diana Bahena (b) (4)	12 Apr 2021 21:50:31

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:21

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:27
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'CABG'	Diana Bahena (b) (4)	12 Apr 2021 21:50:31

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:21

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:27
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'Adverse Event (AE)'	Diana Bahena (b) (4)	12 Apr 2021 21:50:31

US3492107

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 07:59:21

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:53:27
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered empty.	(b) (4) Diana Bahena (b) (4)	12 Apr 2021 21:50:31
	(b) (4)	

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
User entered '11/Jan/2021 11:11'	(b) (4) System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:59:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'I'	(b) (4), (b) (6)	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 18:29:24
User entered '04/Mar/2021 13:04'	System	04 Mar 2021 18:04:09

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:59:21

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.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 14:20:31
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User entered 'I'	(b) (4), (b) (6)	04 Mar 2021 18:04:09

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered '09/Mar/2021 09:20'	(b) (4) System	09 Mar 2021 14:20:45

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:59:21

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Mar 2021 01:41:31
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:43:33
User entered 'I'	(b) (4) (b) (4), (b) (6)	09 Mar 2021 14:20:45

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '30/Mar/2021 01:41'	(b) (4) System	30 Mar 2021 01:41:43

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:59:21

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.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 17:31:21
User entered 'I'	(b) (4), (b) (6)	30 Mar 2021 01:41:43

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '13/Apr/2021 13:31'	(b) (4) System	13 Apr 2021 17:31:07

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 07:59:21

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.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	13 Apr 2021 17:31:21
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 17:31:07

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'USA-US101-2021-MRNA-1273-P301000002'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Yes (Y)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'No (N)'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Richard'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Novak'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '808 S. Wood St'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'Chicago'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'IL'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered '60612'	System	11 Jan 2021 16:11:10

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Mar 2021 18:29:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	11 Jan 2021 16:11:34
User entered 'US'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 10 Jun 2021 07:59:21

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 15:56:14
User entered '5'	System	13 Apr 2021 17:31:07
User entered '4'	System	30 Mar 2021 01:41:43
User entered '3'	System	09 Mar 2021 14:20:45
User entered '2'	System	04 Mar 2021 18:04:09
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:43:12
	(b) (4)	
User entered '1'	System	11 Jan 2021 16:11:31

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:59:21

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered '26/Apr/2021 10:56'	(b) (4) System	26 Apr 2021 15:56:14

US3492107

Folder: SAE USA-US101-2021-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 10 Jun 2021 07:59:21

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.	Richard Novak (b) (4)	26 Apr 2021 16:25:01
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 15:56:14