US3492078 (Prod: UIC Project WISH CRS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 07:56:52

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US3492078
Form: Participant Creation
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Participant ID	US3492078

mRNA-1273-P301 Completion Guidelines

FDA-CBER-2022-1614-2446243

US3492078
Folder: Screening
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	05 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	SCRN

FDA-CBER-2022-1614-2446244

US3492078
Folder: Screening
Form: Demographics
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Date of Birth (MMM yyyy)	(b) (6) 1927
Age	93
Age Units	YEARS
Age (Derived)	93
Sex	Female ☐
	Male ■
Ethnicity	Hispanic or Latino ☐
	Not Hispanic or Latino ■
	Not Reported ☐
	Unknown ☐
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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US3492078
Folder: Screening
Form: Enrollment
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Date of Informed Consent *(dd MMM yyyy)*	5 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 ☐ Amendment 2 ■ Amendment 3 ☐ Amendment 4 ☐ Amendment 5 ☐
Was participant enrolled in the study?	Yes ■ No ☐
If No, indicate reason for screen fail	Withdrew Consent ☐ Inclusion/Exclusion ☐ Cohort Full ☐ Other ☐
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes ☐ No ■
If Yes, previous participant number	
Enrollment Trigger	1

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US3492078
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Did the participant meet all eligibility criteria?	Yes ■ No ☐

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US3492078
Folder: Screening
Form: Medical History Summary
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Were any significant conditions reported?	Yes ■ No ☐

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US3492078
Folder: Screening
Form: Medical History (1)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	CORONARY ARTERY DISEASE
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492078
Folder: Screening
Form: Medical History (2)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492078
Folder: Screening
Form: Medical History (3)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	CONGESTIVE HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492078
Folder: Screening
Form: Medical History (4)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	PROSTATECTOMY
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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US3492078
Folder: Screening
Form: Medical History (5)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	LEFT NEPHRECTOMY FOR KIDNEY CANCER
Start date (dd MMM yyyy)	UN UNK 2013
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ☒
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2013
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2013
Start Year (derived)	2013
Stop Month and Year (derived)	JAN 2013
Stop Year (derived)	2013

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US3492078
Folder: Screening
Form: Medical History (6)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	S/P RESECTION OF BASAL CELL CANCER
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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US3492078
Folder: Screening
Form: Medical History (7)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	S/P CVA
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
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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US3492078
Folder: Screening
Form: Medical History (8)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	S/P CVA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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US3492078
Folder: Screening
Form: Medical History (9)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	S/P CVA WITH RESIDUAL RIGHT LOWER EXTREMITY WEAKNESS AND ATAXIA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes ☒ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

US3492078
Folder: Screening
Form: Medical History (10)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes ■ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492078
Folder: Screening
Form: Medical History (11)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☑ No ☐
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492078
Folder: Screening
Form: Medical History (12)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1932
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1932
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1932
Start Year (derived)	1932
Stop Month and Year (derived)	JAN 1932
Stop Year (derived)	1932

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US3492078
Folder: Screening
Form: Medical History (13)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	S/P CARDIAC ARREST WITH RESUSCITATION
Start date (dd MMM yyyy)	UN UNK 1973
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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US3492078
Folder: Screening
Form: Medical History (14)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	RIGHT LOWER EXTREMITY EDEMA
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ●
	No ○
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	
Stop Year (derived)	

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US3492078
Folder: Screening
Form: Medical History (15)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	CORONARY ARTERY BYPASS GRAFT
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

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US3492078
Folder: Screening
Form: Medical History (16)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1932
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1932
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1932
Start Year (derived)	1932
Stop Month and Year (derived)	JAN 1932
Stop Year (derived)	1932

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US3492078
Folder: Screening
Form: Medical History (17)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Condition	PROSTATE CANCER
Start date (dd MMM yyyy)	UN UNK 1998
Start date completely unknown	False
Condition ongoing at study entry	Yes ☐ No ■
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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US3492078
Folder: Screening
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Were vital signs assessed?	Yes ☒ / No ☐
Date of assessment *(dd MMM yyyy)*	5 SEP 2020
Time of assessment *(00:00-23:59)*	13:49 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 13:49
Height *(xxx.x)*	187.9 cm
Weight *(xxx.x)*	82.5 kg
BMI *(xxx.x)*	23.36686 kg/m^2
BMI units	KG/M2
Temperature *(xxx.x)*	ND - Not Done
Route of measurement	Oral ☐ / Axillary ☐ / Other ☐
If Other, specify	
Pulse *(xxx)*	ND - Not Done
Pulse units	BPM
Respiratory Rate *(xxx)*	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2446266

US3492078
Folder: Screening
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	5 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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US3492078
Folder: Screening
Form: Risk of Exposure
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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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 03:38:46**
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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	

US3492078
Folder: Visit 1 Day 1
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	5 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT1

FDA-CBER-2022-1614-2446270

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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What was the date of randomization? *(dd MMM yyyy)*	05 SEP 2020
What was the participant's randomization number?	190151
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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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Height	ND - Not Done
Weight	ND - Not Done

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	5 SEP 2020
Time of assessment *(00:00-23:59)*	14:49 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 14:49
Temperature *(xxx.x)*	35.6 C
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TYMPANIC
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	5 SEP 2020
Time of assessment *(00:00-23:59)*	16:15 (24 HR)
Vital Signs Date and Time (derived)	5 SEP 2020 16:15
Temperature *(xxx.x)*	35.6 C
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TYMPANIC
Pulse *(xxx)*	56 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	159 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	80 mmHg
Diastolic Blood Pressure units	MMHG

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US3492078
Folder: Visit 1 Day 1
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Was the physical examination performed?	Yes ☒ No ☐
Date of examination *(dd MMM yyyy)*	5 SEP 2020

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

FDA-CBER-2022-1614-2446275

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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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)*	5 SEP 2020
What was the treatment time? *(00:00-23:59)*	15:59 (24 HR)
Treatment Date and Time (derived)	5 SEP 2020 15:59
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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US3492078
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	5 SEP 2020
Collection time *(00:00-23:59)*	14:29 (24 HR)
Collection date and time (derived)	5 SEP 2020 14:29

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US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Collection date *(dd MMM yyyy)*			5 SEP 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:15	5 SEP 2020 14:15
Nasopharyngeal Swab 2	No		

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US3492078
Folder: Visit 1 Day 1
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
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Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

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US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52

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	05 SEP 2020 16:19
PC Close Date & Time	05 SEP 2020 18:49

FDA-CBER-2022-1614-2446280

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**	
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	05 SEP 2020 19:44
PC Close Date & Time	06 SEP 2020 11:59

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52

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**	
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	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-2446282

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52

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**	
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 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-2446283

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52

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**	
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	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-2446284

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52

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**	
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	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-2446285

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52

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**	
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	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-2446286

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52

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**	
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	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-2446287

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52

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	05 SEP 2020 16:19
PC Close Date & Time	05 SEP 2020 18:49

FDA-CBER-2022-1614-2446288

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52

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 ☐
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	05 SEP 2020 19:44
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-2446289

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 2
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	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

FDA-CBER-2022-1614-2446290

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 3
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 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-2446291

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 4
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	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

FDA-CBER-2022-1614-2446292

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 5
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	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-2446293

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 6
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	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-2446294

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 7
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	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-2446295

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 ☐

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US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	05 SEP 2020 16:19
PC Close Date & Time	05 SEP 2020 18:49

FDA-CBER-2022-1614-2446297

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 ☐

FDA-CBER-2022-1614-2446298

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ☐ Yes ☐
PC Time stamp	
PC Open Date & Time	05 SEP 2020 19:44
PC Close Date & Time	06 SEP 2020 11:59

FDA-CBER-2022-1614-2446299

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52

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 ☐

FDA-CBER-2022-1614-2446300

	Yes ☐
PC Time stamp	
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52

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 ☐

FDA-CBER-2022-1614-2446302

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

FDA-CBER-2022-1614-2446303

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52

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 ☐

FDA-CBER-2022-1614-2446304

	Yes ☐
PC Time stamp	
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52

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 ☐

FDA-CBER-2022-1614-2446306

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

FDA-CBER-2022-1614-2446307

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52

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 ☐

FDA-CBER-2022-1614-2446308

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

FDA-CBER-2022-1614-2446309

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52

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 ☐

FDA-CBER-2022-1614-2446310

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	
PC Open Date & Time	11 SEP 2020 12:00
PC Close Date & Time	12 SEP 2020 11:59

FDA-CBER-2022-1614-2446311

US3492078
Folder: Safety Call Day 8 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	14 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446312

US3492078
Folder: Safety Call Day 8 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446313

US3492078
Folder: Safety Call Day 15 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	21 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446314

US3492078
Folder: Safety Call Day 15 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446315

US3492078
Folder: Safety Call Day 22 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 SEP 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446316

US3492078
Folder: Safety Call Day 22 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446317

US3492078
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	VISIT2

FDA-CBER-2022-1614-2446318

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Timepoint	Pre-Dose ■ Post-Dose ☐
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 OCT 2020
Time of assessment *(00:00-23:59)*	13:24 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 13:24
Temperature *(xxx.x)*	97.3 F
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TYMPANIC
Pulse *(xxx)*	60 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	78 mmHg
Diastolic Blood Pressure units	MMHG

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Timepoint	Pre-Dose ☐ Post-Dose ■
Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	02 OCT 2020
Time of assessment *(00:00-23:59)*	14:55 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 14:55
Temperature *(xxx.x)*	36 C
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TYMPANIC
Pulse *(xxx)*	62 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	71 mmHg
Diastolic Blood Pressure units	MMHG

FDA-CBER-2022-1614-2446320

US3492078
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	02 OCT 2020

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

FDA-CBER-2022-1614-2446321

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

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)*	02 OCT 2020
What was the treatment time? *(00:00-23:59)*	14:53 (24 HR)
Treatment Date and Time (derived)	02 OCT 2020 14:53
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

FDA-CBER-2022-1614-2446322

US3492078
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	02 OCT 2020
Collection time *(00:00-23:59)*	13:43 (24 HR)
Collection date and time (derived)	02 OCT 2020 13:43

FDA-CBER-2022-1614-2446323

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Collection date *(dd MMM yyyy)*			02 OCT 2020
Lab Test	Was the sample collected?	Collection time *(00:00 - 23:59)*	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:50	02 OCT 2020 13:50
Nasopharyngeal Swab 2	No		

FDA-CBER-2022-1614-2446324

US3492078
Folder: Visit 2 Day 29 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446325

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52

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**	96.8 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 OCT 2020 15:32
PC Open Date & Time	02 OCT 2020 15:13
PC Close Date & Time	02 OCT 2020 17:43

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52

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**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ☐ No ■
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	02 OCT 2020 18:39
PC Open Date & Time	02 OCT 2020 18:38
PC Close Date & Time	03 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 2

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °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	03 OCT 2020 12:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52

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**	98.0 °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	04 OCT 2020 13:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52

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**	97.9 °F
Was any **MEDICATION TAKEN today for pain or fever**?	Yes ○
	No ●
Please confirm reason for pain or fever medication (may select more than one):	
PC Time Stamp	05 OCT 2020 16:14
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52

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**	98.0 °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	06 OCT 2020 18:49
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52

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	07 OCT 2020 20:51
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 7

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

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

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

Please record your temperature each day. If you measure your temperature more than once on a given day, please report the highest temperature for that day.
If your temperature is equal to or over 100.4°F at Day 7, you will be prompted by the app each day after Day 7 to confirm temperature until it has returned to below 100.4°F.

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

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

Was **TEMPERATURE** taken?	Yes ●
	No ○
Please record your **TEMPERATURE in °F**	98.1 °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	08 OCT 2020 18:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52

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	02 OCT 2020 15:32
PC Open Date & Time	02 OCT 2020 15:13
PC Close Date & Time	02 OCT 2020 17:43

FDA-CBER-2022-1614-2446334

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52

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	02 OCT 2020 18:39
PC Open Date & Time	02 OCT 2020 18:38
PC Close Date & Time	03 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 2
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	03 OCT 2020 12:02
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 3
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	04 OCT 2020 13:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-2446337

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 4
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 - **SWELLING/HARDNESS AT INJECTION SITE (in mm)** Measure the largest size across any injection site swelling/hardness with the ruler provided.	4
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	05 OCT 2020 16:15
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-2446338

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 5
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	06 OCT 2020 18:49
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 6
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 20:51
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

FDA-CBER-2022-1614-2446340

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 7
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	08 OCT 2020 18:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-2446341

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 ☐

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 OCT 2020 15:33
PC Open Date & Time	02 OCT 2020 15:13
PC Close Date & Time	02 OCT 2020 17:43

FDA-CBER-2022-1614-2446343

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

FDA-CBER-2022-1614-2446344

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52

Did you receive any **MEDICAL ATTENTION (doctor visit, other)** for any illness or symptoms?	No ■ Yes ☐
PC Time stamp	02 OCT 2020 18:40
PC Open Date & Time	02 OCT 2020 18:38
PC Close Date & Time	03 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52

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 ■

FDA-CBER-2022-1614-2446346

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	03 OCT 2020 12:03
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

FDA-CBER-2022-1614-2446347

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52

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 ■

FDA-CBER-2022-1614-2446348

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	04 OCT 2020 13:10
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

FDA-CBER-2022-1614-2446349

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52

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 ■

FDA-CBER-2022-1614-2446350

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	05 OCT 2020 16:15
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

FDA-CBER-2022-1614-2446351

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52

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 ■

FDA-CBER-2022-1614-2446352

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	06 OCT 2020 18:49
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

FDA-CBER-2022-1614-2446353

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52

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 ■

FDA-CBER-2022-1614-2446354

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	07 OCT 2020 20:51
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52

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 ■

FDA-CBER-2022-1614-2446356

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52

	Yes ☐
PC Time stamp	08 OCT 2020 18:45
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

FDA-CBER-2022-1614-2446357

US3492078
Folder: Safety Call Day 36 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	09 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446358

US3492078
Folder: Safety Call Day 36 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446359

US3492078
Folder: Safety Call Day 43 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	19 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446360

US3492078
Folder: Safety Call Day 43 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446361

US3492078
Folder: Safety Call Day 50 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	23 OCT 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446362

US3492078
Folder: Safety Call Day 50 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446363

US3492078
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	06 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT3

FDA-CBER-2022-1614-2446364

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	06 NOV 2020
Time of assessment *(00:00-23:59)*	15:15 (24 HR)
Vital Signs Date and Time (derived)	06 NOV 2020 15:15
Temperature *(xxx.x)*	37.4 C
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TYMPANIC
Pulse *(xxx)*	78 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	66 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

FDA-CBER-2022-1614-2446365

US3492078
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was the physical examination performed?	Yes ☑ No ☐
Date of examination *(dd MMM yyyy)*	06 NOV 2020

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

US3492078
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	06 NOV 2020
Collection time *(00:00-23:59)*	15:26 (24 HR)
Collection date and time (derived)	06 NOV 2020 15:26

US3492078
Folder: Visit 3 Day 57 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446368

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	08 NOV 2020 18:01:13
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2020 00:01
Patient Cloud Close Date & Time	16 NOV 2020 23:59

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2020 00:01
Patient Cloud Close Date & Time	23 NOV 2020 23:59

FDA-CBER-2022-1614-2446373

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 20:23:13
Patient Cloud Open Date & Time	23 NOV 2020 00:01
Patient Cloud Close Date & Time	27 NOV 2020 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-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 NOV 2020 19:14:07
Patient Cloud Open Date & Time	30 NOV 2020 00:01
Patient Cloud Close Date & Time	04 DEC 2020 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 DEC 2020 17:02:03
Patient Cloud Open Date & Time	07 DEC 2020 00:01
Patient Cloud Close Date & Time	11 DEC 2020 23:59

FDA-CBER-2022-1614-2446376

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	14 DEC 2020 20:54:05
Patient Cloud Open Date & Time	14 DEC 2020 00:01
Patient Cloud Close Date & Time	18 DEC 2020 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	21 DEC 2020 00:03:15
Patient Cloud Open Date & Time	21 DEC 2020 00:01
Patient Cloud Close Date & Time	25 DEC 2020 23:59

FDA-CBER-2022-1614-2446378

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	28 DEC 2020 23:13:52
Patient Cloud Open Date & Time	28 DEC 2020 00:01
Patient Cloud Close Date & Time	01 JAN 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	04 JAN 2021 00:04:37
Patient Cloud Open Date & Time	04 JAN 2021 00:01
Patient Cloud Close Date & Time	08 JAN 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 23:37:48
Patient Cloud Open Date & Time	11 JAN 2021 00:01
Patient Cloud Close Date & Time	15 JAN 2021 23:59

FDA-CBER-2022-1614-2446381

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 JAN 2021 00:03:56
Patient Cloud Open Date & Time	18 JAN 2021 00:01
Patient Cloud Close Date & Time	22 JAN 2021 23:59

FDA-CBER-2022-1614-2446382

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	25 JAN 2021 16:33:03
Patient Cloud Open Date & Time	25 JAN 2021 00:01
Patient Cloud Close Date & Time	29 JAN 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 FEB 2021 19:58:34
Patient Cloud Open Date & Time	01 FEB 2021 00:01
Patient Cloud Close Date & Time	05 FEB 2021 23:59

FDA-CBER-2022-1614-2446384

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ■ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 FEB 2021 21:28:56
Patient Cloud Open Date & Time	08 FEB 2021 00:01
Patient Cloud Close Date & Time	12 FEB 2021 23:59

FDA-CBER-2022-1614-2446385

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	15 FEB 2021 19:22:29
Patient Cloud Open Date & Time	15 FEB 2021 00:01
Patient Cloud Close Date & Time	19 FEB 2021 23:59

FDA-CBER-2022-1614-2446386

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	22 FEB 2021 00:02:24
Patient Cloud Open Date & Time	22 FEB 2021 00:01
Patient Cloud Close Date & Time	26 FEB 2021 23:59

FDA-CBER-2022-1614-2446387

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	01 MAR 2021 00:04:28
Patient Cloud Open Date & Time	01 MAR 2021 00:01
Patient Cloud Close Date & Time	05 MAR 2021 23:59

FDA-CBER-2022-1614-2446388

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	08 MAR 2021 07:43:03
Patient Cloud Open Date & Time	08 MAR 2021 00:01
Patient Cloud Close Date & Time	12 MAR 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	15 MAR 2021 21:07:55
Patient Cloud Open Date & Time	15 MAR 2021 00:01
Patient Cloud Close Date & Time	19 MAR 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	24 MAR 2021 12:13:12
Patient Cloud Open Date & Time	22 MAR 2021 00:01
Patient Cloud Close Date & Time	26 MAR 2021 23:59

FDA-CBER-2022-1614-2446391

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	31 MAR 2021 17:26:09
Patient Cloud Open Date & Time	29 MAR 2021 00:01
Patient Cloud Close Date & Time	02 APR 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	05 APR 2021 00:02:59
Patient Cloud Open Date & Time	05 APR 2021 00:01
Patient Cloud Close Date & Time	09 APR 2021 23:59

FDA-CBER-2022-1614-2446393

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	12 APR 2021 07:24:42
Patient Cloud Open Date & Time	12 APR 2021 00:01
Patient Cloud Close Date & Time	16 APR 2021 23:59

FDA-CBER-2022-1614-2446394

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	19 APR 2021 06:59:33
Patient Cloud Open Date & Time	19 APR 2021 00:01
Patient Cloud Close Date & Time	23 APR 2021 23:59

FDA-CBER-2022-1614-2446395

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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	28 APR 2021 07:15:54
Patient Cloud Open Date & Time	26 APR 2021 00:01
Patient Cloud Close Date & Time	30 APR 2021 23:59

FDA-CBER-2022-1614-2446396

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 MAY 2021 00:01
Patient Cloud Close Date & Time	07 MAY 2021 23:59

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 MAY 2021 00:01
Patient Cloud Close Date & Time	14 MAY 2021 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and 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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 MAY 2021 00:01
Patient Cloud Close Date & Time	04 JUN 2021 23:59

FDA-CBER-2022-1614-2446406

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 JUN 2021 00:01
Patient Cloud Close Date & Time	11 JUN 2021 23:59

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 JUN 2021 00:01
Patient Cloud Close Date & Time	18 JUN 2021 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 JUN 2021 00:01
Patient Cloud Close Date & Time	25 JUN 2021 23:59

FDA-CBER-2022-1614-2446412

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 JUN 2021 00:01
Patient Cloud Close Date & Time	02 JUL 2021 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 JUL 2021 00:01
Patient Cloud Close Date & Time	09 JUL 2021 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 JUL 2021 00:01
Patient Cloud Close Date & Time	16 JUL 2021 23:59

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2446421

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2021 00:01
Patient Cloud Close Date & Time	06 AUG 2021 23:59

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 AUG 2021 00:01
Patient Cloud Close Date & Time	13 AUG 2021 23:59

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 AUG 2021 00:01
Patient Cloud Close Date & Time	20 AUG 2021 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 AUG 2021 00:01
Patient Cloud Close Date & Time	03 SEP 2021 23:59

FDA-CBER-2022-1614-2446432

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 SEP 2021 00:01
Patient Cloud Close Date & Time	10 SEP 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 SEP 2021 00:01
Patient Cloud Close Date & Time	17 SEP 2021 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 SEP 2021 00:01
Patient Cloud Close Date & Time	24 SEP 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 SEP 2021 00:01
Patient Cloud Close Date & Time	01 OCT 2021 23:59

FDA-CBER-2022-1614-2446440

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	08 OCT 2021 23:59

FDA-CBER-2022-1614-2446442

TIMEPOINT	DAY 404
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	15 OCT 2021 23:59

FDA-CBER-2022-1614-2446444

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 OCT 2021 00:01
Patient Cloud Close Date & Time	22 OCT 2021 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2021 00:01
Patient Cloud Close Date & Time	29 OCT 2021 23:59

FDA-CBER-2022-1614-2446448

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 NOV 2021 00:01
Patient Cloud Close Date & Time	05 NOV 2021 23:59

FDA-CBER-2022-1614-2446450

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	12 NOV 2021 23:59

FDA-CBER-2022-1614-2446452

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 NOV 2021 00:01
Patient Cloud Close Date & Time	19 NOV 2021 23:59

FDA-CBER-2022-1614-2446454

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446457

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 NOV 2021 00:01
Patient Cloud Close Date & Time	03 DEC 2021 23:59

FDA-CBER-2022-1614-2446458

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 DEC 2021 00:01
Patient Cloud Close Date & Time	10 DEC 2021 23:59

FDA-CBER-2022-1614-2446460

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 ≥ 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 ☐

US3492078
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Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 DEC 2021 00:01
Patient Cloud Close Date & Time	17 DEC 2021 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446463

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 DEC 2021 00:01
Patient Cloud Close Date & Time	24 DEC 2021 23:59

FDA-CBER-2022-1614-2446464

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	27 DEC 2021 00:01
Patient Cloud Close Date & Time	31 DEC 2021 23:59

FDA-CBER-2022-1614-2446466

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	07 JAN 2022 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
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TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

FDA-CBER-2022-1614-2446469

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 JAN 2022 00:01
Patient Cloud Close Date & Time	14 JAN 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	21 JAN 2022 23:59

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446473

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JAN 2022 00:01
Patient Cloud Close Date & Time	28 JAN 2022 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 JAN 2022 00:01
Patient Cloud Close Date & Time	04 FEB 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 FEB 2022 00:01
Patient Cloud Close Date & Time	11 FEB 2022 23:59

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TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 FEB 2022 00:01
Patient Cloud Close Date & Time	18 FEB 2022 23:59

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 ≥ 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 ☐

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Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 FEB 2022 00:01
Patient Cloud Close Date & Time	25 FEB 2022 23:59

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Folder: New Safety Follow Up Diary (1)
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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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 FEB 2022 00:01
Patient Cloud Close Date & Time	04 MAR 2022 23:59

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 MAR 2022 00:01
Patient Cloud Close Date & Time	11 MAR 2022 23:59

FDA-CBER-2022-1614-2446486

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	14 MAR 2022 00:01
Patient Cloud Close Date & Time	18 MAR 2022 23:59

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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 ≥ 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 ☐

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Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	21 MAR 2022 00:01
Patient Cloud Close Date & Time	25 MAR 2022 23:59

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 ≥ 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 ☐

US3492078
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Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	28 MAR 2022 00:01
Patient Cloud Close Date & Time	01 APR 2022 23:59

FDA-CBER-2022-1614-2446492

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446493

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	04 APR 2022 00:01
Patient Cloud Close Date & Time	08 APR 2022 23:59

FDA-CBER-2022-1614-2446494

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 ≥ 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 ☐

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

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Form: Safety Follow Up Diary
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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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 APR 2022 00:01
Patient Cloud Close Date & Time	22 APR 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 APR 2022 00:01
Patient Cloud Close Date & Time	29 APR 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	02 MAY 2022 00:01
Patient Cloud Close Date & Time	06 MAY 2022 23:59

FDA-CBER-2022-1614-2446502

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	09 MAY 2022 00:01
Patient Cloud Close Date & Time	13 MAY 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	16 MAY 2022 00:01
Patient Cloud Close Date & Time	20 MAY 2022 23:59

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	23 MAY 2022 00:01
Patient Cloud Close Date & Time	27 MAY 2022 23:59

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TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	30 MAY 2022 00:01
Patient Cloud Close Date & Time	03 JUN 2022 23:59

FDA-CBER-2022-1614-2446510

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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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	06 JUN 2022 00:01
Patient Cloud Close Date & Time	10 JUN 2022 23:59

FDA-CBER-2022-1614-2446512

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	13 JUN 2022 00:01
Patient Cloud Close Date & Time	17 JUN 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2022 00:01
Patient Cloud Close Date & Time	24 JUN 2022 23:59

FDA-CBER-2022-1614-2446516

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 ≥ 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 ☐

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

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	08 JUL 2022 23:59

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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
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Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	18 JUL 2022 00:01
Patient Cloud Close Date & Time	22 JUL 2022 23:59

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

Please contact your study clinic immediately. Click below to confirm that you have read this 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 JUL 2022 00:01
Patient Cloud Close Date & Time	29 JUL 2022 23:59

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 ≥ 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 ☐

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	01 AUG 2022 00:01
Patient Cloud Close Date & Time	05 AUG 2022 23:59

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446529

Please contact your study clinic immediately. Click below to confirm that you have read this 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 AUG 2022 00:01
Patient Cloud Close Date & Time	12 AUG 2022 23:59

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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 ≥ 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 ☐

US3492078
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Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2022 00:01
Patient Cloud Close Date & Time	19 AUG 2022 23:59

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2022 00:01
Patient Cloud Close Date & Time	26 AUG 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	29 AUG 2022 00:01
Patient Cloud Close Date & Time	02 SEP 2022 23:59

FDA-CBER-2022-1614-2446536

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TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	05 SEP 2022 00:01
Patient Cloud Close Date & Time	09 SEP 2022 23:59

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

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	12 SEP 2022 00:01
Patient Cloud Close Date & Time	16 SEP 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2022 00:01
Patient Cloud Close Date & Time	23 SEP 2022 23:59

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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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2022 00:01
Patient Cloud Close Date & Time	30 SEP 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	03 OCT 2022 00:01
Patient Cloud Close Date & Time	07 OCT 2022 23:59

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 ≥ 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 ☐

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2022 00:01
Patient Cloud Close Date & Time	14 OCT 2022 23:59

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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 ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2022 00:01
Patient Cloud Close Date & Time	21 OCT 2022 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446551

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	24 OCT 2022 00:01
Patient Cloud Close Date & Time	28 OCT 2022 23:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

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 ≥ 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 ☐

FDA-CBER-2022-1614-2446553

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	31 OCT 2022 00:01
Patient Cloud Close Date & Time	04 NOV 2022 23:59

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No ☐ Yes ☐
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature ≥ 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 ☐

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately ☐
Date and time of submission	
Patient Cloud Open Date & Time	07 NOV 2022 00:01
Patient Cloud Close Date & Time	11 NOV 2022 23:59

FDA-CBER-2022-1614-2446556

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		28 FEB 2021 19:30:29

US3492078
Folder: Safety Call Day 85 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	24 NOV 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2446558

US3492078
Folder: Safety Call Day 85 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446559

US3492078
Folder: Safety Call Day 119 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	30 DEC 2020
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments *If Contact Not Made, please provide Comments*	

FDA-CBER-2022-1614-2446560

US3492078
Folder: Safety Call Day 119 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446561

US3492078
Folder: Safety Call Day 149 (1)
Form: Safety Call
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	28 JAN 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446562

US3492078
Folder: Safety Call Day 149 (1)
Form: Continuing
Data signed: (b) (4) **15 Feb 2021 03:38:46**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446563

US3492078
Folder: Safety Call Day 179 (1)
Form: Safety Call
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	26 FEB 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446564

US3492078
Folder: Safety Call Day 179 (1)
Form: Continuing
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446565

US3492078
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Was this visit performed?	Yes ☑ No ☐
Visit date (dd MMM yyyy)	31 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ☑
Folder OID	VISIT4

FDA-CBER-2022-1614-2446566

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Were vital signs assessed?	Yes ■ No ☐
Date of assessment *(dd MMM yyyy)*	31 MAR 2021
Time of assessment *(00:00-23:59)*	13:46 (24 HR)
Vital Signs Date and Time (derived)	31 MAR 2021 13:46
Temperature *(xxx.x)*	36.3 C
Route of measurement	Oral ☐ Axillary ☐ Other ■
If Other, specify	TYMPANIC
Pulse *(xxx)*	81 beats/min
Pulse units	BPM
Respiratory Rate *(xxx)*	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure *(xxx)*	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure *(xxx)*	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3492078
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Was the physical examination performed?	Yes ■ No ☐
Date of examination *(dd MMM yyyy)*	31 MAR 2021

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

FDA-CBER-2022-1614-2446568

US3492078
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	31 MAR 2021
Collection time *(00:00-23:59)*	14:10 (24 HR)
Collection date and time (derived)	31 MAR 2021 14:10

FDA-CBER-2022-1614-2446569

US3492078
Folder: Visit 4 Day 209 (1)
Form: Continuing
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446570

US3492078
Folder: Safety Call Day 239 (1)
Form: Safety Call
Data signed: (b) (4) **30 Apr 2021 21:45:15**
Generated On: 10 Jun 2021 07:56:52

Was Contact Attempted?	Yes ■ No ☐
Date of Contact or Contact Attempt *(dd MMM yyyy)*	29 APR 2021
Please select one status for the follow-up contact	Contact Made ■ Contact Not Made ☐
Comments	
If Contact Not Made, please provide Comments	

FDA-CBER-2022-1614-2446571

US3492078
Folder: Safety Call Day 239 (1)
Form: Continuing
Data signed: (b) (4) **30 Apr 2021 21:45:15**
Generated On: 10 Jun 2021 07:56:52

Is the participant continuing to the next visit?	Yes ■ No ☐
Continuing Flag	1

FDA-CBER-2022-1614-2446572

US3492078
Folder: Safety Call Day 269 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52

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	

Is the participant continuing to the next visit?	Yes ☐ No ☐
Continuing Flag	

US3492078
Folder: Covid-19 Assessment (1)
Form: COVID-19 Contact
Generated On: 10 Jun 2021 07:56:52

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled ☐
	Clinical Visit - Unscheduled ☐
	Safety Call ☐
	Convalescent Tele-visit ☐
Has the subject reported symptoms of SARS-COV-2?	Yes ☐
	No ☐

FDA-CBER-2022-1614-2446575

US3492078
Folder: Covid-19 Assessment (1)
Form: Generate Next COVID-19 Assessment
Generated On: 10 Jun 2021 07:56:52

Generate Next COVID-19 Assessment	Yes ☐ No ☐

FDA-CBER-2022-1614-2446576

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Was this visit performed?	Yes ■ No ☐
Visit date (dd MMM yyyy)	15 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home ☐ Clinic ■
Folder OID	UNBLND_DECIDE

FDA-CBER-2022-1614-2446577

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

Date of updated informed consent *(dd MMM yyyy)*	15 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes ■ No ☐
Under what version of the Protocol was the Participant unblinded?	Amendment 5 ☐ Amendment 6 or later ■
Date of unblinding *(dd MMM yyyy)*	15 JAN 2021
Participant randomization assignment	mRNA-1273 ■ Placebo ☐
Actual Dose 1	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Actual Dose 2	mRNA-1273 ■ Placebo ☐ Not Administered ☐
Will participant receive mRNA-1273?	Yes ☐ No ■
Placebo Only Flag	
Continuing with mRNA-1273	

FDA-CBER-2022-1614-2446578

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Was the sample collected?	Yes ☑ No ☐
Collection date *(dd MMM yyyy)*	15 JAN 2021
Collection time *(00:00-23:59)*	15:15 (24 HR)
Collection date and time (derived)	15 JAN 2021 15:15

FDA-CBER-2022-1614-2446579

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Was the sample collected?	Yes ■ No ☐
Collection date *(dd MMM yyyy)*	15 JAN 2021
Collection time *(00:00 - 23:59)*	15:30
Collection Date and Time (derived)	15 JAN 2021 15:30

FDA-CBER-2022-1614-2446580

US3492078
Folder: Adverse Events
Form: Adverse Events Summary
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Did the participant experience any adverse events?	Yes ■ No ☐

If Yes, enter details on the Adverse Events form.

FDA-CBER-2022-1614-2446581

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Data signed: (b) (4) **30 Apr 2021 21:45:14**
Generated On: 10 Jun 2021 07:56:52

AEID	
Adverse event	SORENESS AT INJECTION SITE
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 SEP 2020
Start time *(00:00-23:59)*	17:00 (24 HR)
AE start date and time (derived)	5 SEP 2020 17:00
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	7 SEP 2020
End time *(00:00-23:59)*	12:00 (24 HR)
AE End Date and Time (derived)	7 SEP 2020 12:00
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ☐ Related ■ Not Applicable ☐
Relationship to Study Procedure	Not Related ☐ Related ■ Not Applicable ☐
Action taken with investigational product	None ■ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ☐
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SOLICITED AE BUT COULD NOT GET EPRO TO WORK DESPITE CALLS TO MEDIDATA HELPDESK-CORRECTION-NOT SOLICITED SINCE NOT CAPTURED ON DIARY AND REPORTED VERBALLY TO SITE
Serious Adverse Event Derived (CSA Programming Field Ony)	0

Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Data signed: (b) (4) **30 Apr 2021 21:45:14**
Generated On: 10 Jun 2021 07:56:52

AEID	USA-US101-2020-MRNA-1273-P30 1000006
Adverse event	HEMATOMA OF THE R LEG
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)*	03 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	13 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ☐ Grade 2/Moderate ☐ Grade 3/Severe ■ Grade 4 ☐
Is the adverse event serious?	Yes ■ No ☐
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date *(dd MMM yyyy)*	10 NOV 2020
Hospital Discharge Date *(dd MMM yyyy)*	17 NOV 2020
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

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 ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

	PARTICIPANT WAS WORKING OUT ON TOTAL GYM MACHINE AND INJURED RIGHT UPPER LEG MUSCLE. ROM AND STRENGTH WITHIN NORMAL LIMITS AND BASELINE FOR PARTICIPANT. SUBJECT HOSPITALIZED 10NOV 2020 THROUGH 17NOV2020 FOR PAIN AND SWELLING IN R LEG. RLE CT WHICH SHOWED LARGE INTRAMUSCULAR HEMATOMA OF THE VASTUS LATERALUS WITH MULTIPLE FOCI OF ACTIVE EXTRAVASATION FROM BRANCHES OF THE PROFUNDA FEMORAL ARTERY. NO DVT. APIXABAN HELD AND ASA DISCONTINUED. COLONOSCOPY PERFORMED FOR SIGNS OF BLEEDING AND COMPLAINT OF INTERMITTENT DIARRHEA THAT HE DID NOT REPORT AT D57 NOR ON EDIARY OR SAFETY CALLS. OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. VASCULAR ANGIOGRAM AND EMBOLIZATION PERFORMED ON13NOV2020. AT DISCHARGE APIXABAN RESTARTED AT 2.5MG BID
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **30 Apr 2021 21:45:14**
Generated On: 10 Jun 2021 07:56:52

AEID	
Adverse event	DIARRHEA
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)*	07 NOV 2020
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ☐ No ■
If not Ongoing, end date *(dd MMM yyyy)*	18 NOV 2020
End time *(00:00-23:59)*	
AE End Date and Time (derived)	
Severity	Grade 1/Mild ■ Grade 2/Moderate ☐ Grade 3/Severe ☐ Grade 4 ☐
Is the adverse event serious?	Yes ☐ No ■
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date *(dd MMM yyyy)*	
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ☐ Unknown ☐
Number of Days in ICU	

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ■ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ☐ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT HAS REPORTED DIARRHEA, HOSPITAL RECORDS INDICATE 3 WEEKS, HOWEVER, CONFIRMATION WITH SON IS 3 DAYS PRIOR TO ADMISSION WHICH WOULD BE MORE CONSISTENT WITH NO COMMENTS IN E DIARIES OR SAFETY CALLS

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Data signed: (b) (4) **30 Apr 2021 21:45:14**
Generated On: 10 Jun 2021 07:56:52

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

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **30 Apr 2021 21:45:14**
Generated On: 10 Jun 2021 07:56:52

AEID	USA-US101-2021-MRNA-1273-P30 1000012
Adverse event	RIGHT LUNG PLEURAL EFFUSION
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)*	24 APR 2021
Start time *(00:00-23:59)*	
AE start date and time (derived)	
Ongoing?	Yes ■ No ☐
If not Ongoing, end date *(dd MMM yyyy)*	
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	True
Hospital Admission Date *(dd MMM yyyy)*	24 APR 2021
Hospital Discharge Date *(dd MMM yyyy)*	
Admitted to ICU?	Yes ☐ No ■ Unknown ☐

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 ■ Related ☐ Not Applicable ☐
Relationship to Study Procedure	Not Related ■ Related ☐ Not Applicable ☐
Action taken with investigational product	None ☐ Dose Delayed ☐ Investigational Product Withdrawn ☐ Not Applicable ■
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal ☐ Not Recovered/Not Resolved ☐ Recovered/Resolved ☐ Recovered/Resolved with Sequelae ☐ Recovering/Resolving ■ Unknown ☐
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	

Narrative

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Data signed: (b) (4) **30 Apr 2021 21:45:14**
Generated On: 10 Jun 2021 07:56:52

	SUBJECT'S SON REPORTED DURING SAFETY CALL ON 29APR2021 THAT SUBJECT WAS HOSPITALIZED FOR RIGHT PLEURAL EFFUSION ON 24APR2021, CHEST TUBE PLACED ON SAME DAY. COVID PCR TEST NEGATIVE ON ADMISSON. CURRENTLY UNDER OBSERVATION. MEDICAL RECORDS REQUESTED.
Serious Adverse Event Derived (CSA Programming Field Ony)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Were any prior/concomitant medications and/or vaccinations taken?	Yes ■ No ☐

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

FDA-CBER-2022-1614-2446594

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	ASPIRIN
Prophylaxis	Yes ☐ No ■
Indication	CORONARY ARTERY DISEASE
Dose per administration	81
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2446595

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2019
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ■
Indication	S/P HISTORY OF MULTIPLE CVA'S
Dose per administration	5
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐

FDA-CBER-2022-1614-2446597

	Intraocular ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	10 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	LASIX
Prophylaxis	Yes ☐ No ■
Indication	CONGESTIVE HEART FAILURE
Dose per administration	20
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2018
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	ATORVASTATIN
Prophylaxis	Yes ☐ No ■
Indication	HYPERLIPIDEMIA
Dose per administration	40
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2446601

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2003
Start date completely unknown	False
Ongoing?	Yes ■ No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐ No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐ 803 ☐ 804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	METOPROLOL
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FIBRILLATION
Dose per administration	25
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2446603

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2016
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	17 NOV 2020
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	SERTRALINE
Prophylaxis	Yes ☐ No ■
Indication	DEPRESSION
Dose per administration	25
Dose unit	mg ■ ug ☐ mL ☐ g ☐ IU ☐ tablet ☐ capsule ☐ puff ☐ Other ☐
If dose unit is Other, specify	
Frequency	once daily ■ twice daily ☐ three times daily ☐ four times daily ☐ every other day ☐ every week ☐ every month ☐ as needed ☐ once ☐ unknown ☐ other ☐
If frequency is Other, specify	
Route of administration	Oral ■ Topical ☐ Subcutaneous ☐ Transdermal ☐ Intraocular ☐

FDA-CBER-2022-1614-2446605

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	UN UNK 2017
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	ELIQUIS
Prophylaxis	Yes ☐ No ■
Indication	CEREBROVASCULAR DISEASE AND ATRIAL FIBRILLATION
Dose per administration	2.5
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 ☐
	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	16 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	2
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Data signed: (b) (4) **26 Apr 2021 16:23:39**
Generated On: 10 Jun 2021 07:56:52

Name of Medication	METOPROLOL XL
Prophylaxis	Yes ☐ No ■
Indication	ATRIAL FIBRILLATION
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 ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	18 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ☐
	No ■
If not Ongoing, End date *(dd MMM yyyy)*	01 MAR 2021
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

Name of Medication	IRON
Prophylaxis	Yes ■ No ☐
Indication	LOW HEMOGLOBLIN
Dose per administration	27
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 ☐

	Intramuscular ☐
	Respiratory (Inhalation) ☐
	Intralesional ☐
	Intraperiteoneal ☐
	Nasal ☐
	Vaginal ☐
	Rectal ☐
	Intravenous ☐
	Intravenous Bolus ☐
	Intravenous Drip ☐
	Other ☐
If route of administration is Other, specify	
Start date *(dd MMM yyyy)*	11 NOV 2020
Start date completely unknown	False
Ongoing?	Yes ■
	No ☐
If not Ongoing, End date *(dd MMM yyyy)*	
Was this medication taken for solicited event?	Yes ☐
	No ■
Separate Dosage Number (derived)	1
Interval Dosage Unit Number (derived)	1
Interval Dosage Definition (derived)	802 ☐
	803 ☐
	804 ■

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Data signed: (b) (4) **15 Feb 2021 03:38:45**
Generated On: 10 Jun 2021 07:56:52

Were any concomitant procedures performed?	Yes ■ No ☐

If yes, please complete Concomitant Procedures form.

FDA-CBER-2022-1614-2446613

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures
Data signed: (b) (4) **30 Apr 2021 21:45:15**
Generated On: 10 Jun 2021 07:56:52

Procedure/Surgery date *(dd MMM yyyy)*	Procedure/Surgery	Indication	If indication is Other, specify
13 NOV 2020	ARTERIAL ANGIOGRAM WITH EMBOLIZATION	Adverse Event	
11 NOV 2020	COLONOSCOPY	Adverse Event	
11 NOV 2020	CT RIGHT LOWER EXTREMITY	Adverse Event	
10 NOV 2020	3 UNITS OF PRBC INFUSION	Adverse Event	
24 APR 2021	CHEST TUBE PLACEMENT TO DRAIN PLEURAL EFFUSION	Adverse Event	

US3492078
Folder: End of Study (1)
Form: Dosing Discontinuation
Generated On: 10 Jun 2021 07:56:52

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	

US3492078
Folder: End of Study (1)
Form: End of Study / Study Discontinuation
Generated On: 10 Jun 2021 07:56:52

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 ☐

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	4

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (1)
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	4
Date of submission (Pre-filled from custom function)	23/NOV/2020 20:08
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

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (2)
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	4
Date of submission (Pre-filled from custom function)	30/NOV/2020 21:07
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

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (3)
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	4
Date of submission (Pre-filled from custom function)	04/FEB/2021 14:01
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

FDA-CBER-2022-1614-2446620

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (4)
Data signed: (b) (4) **26 Mar 2021 01:41:47**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2020-MRNA-1273-P301000006
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	4
Date of submission (Pre-filled from custom function)	23/FEB/2021 14:50
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

FDA-CBER-2022-1614-2446621

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Data signed: (b) (4) **30 Apr 2021 21:45:15**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2021-MRNA-1273-P301000012
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	1

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form (1)
Data signed: (b) (4) **30 Apr 2021 21:45:15**
Generated On: 10 Jun 2021 07:56:52

SAEID	USA-US101-2021-MRNA-1273-P301000012
Serious	Yes ■ No ☐
Death	Yes ☐ No ■
Life threatening	Yes ☐ No ■
Requires inpatient or prolongation of existing Hospitalization	Yes ■ No ☐
Persistent or significant disability or incapacity	Yes ☐ No ■
Congenital anomaly or birth defect	Yes ☐ No ■
Other medically important event	Yes ☐ No ■
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)	1
Date of submission (Pre-filled from custom function)	30/APR/2021 11:27
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

FDA-CBER-2022-1614-2446623

US3492078
Form: Participant Creation
Generated On: 10 Jun 2021 07:56:52
Participant ID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'US3492078'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 18:40:42

FDA-CBER-2022-1614-2446625

US3492078
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:51:17

US3492078
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '05 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 18:40:43

US3492078
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Clinic (Clinic)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:51:17

US3492078
Folder: Screening
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'SCRN'	System	05 Sep 2020 19:51:17

FDA-CBER-2022-1614-2446629

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered (b) (6) 1927'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 18:40:44

FDA-CBER-2022-1614-2446630

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Age

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '93'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446631

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Age Units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'YEARS'	System	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446632

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Age (Derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '93'	System	05 Sep 2020 19:52:56

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Male (M)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446634

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Ethnicity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '1'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446636

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446637

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Asian

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446638

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
American Indian or Alaska Native

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Native Hawaiian or other Pacific Islander

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446640

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446641

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446643

US3492078
Folder: Screening
Form: Demographics
Generated On: 10 Jun 2021 07:56:52
Not reported

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:36

FDA-CBER-2022-1614-2446644

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Date of Informed Consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Month and Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Sep 2020'	System	05 Sep 2020 19:52:56

FDA-CBER-2022-1614-2446646

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Year of Informed Consent (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2020'	System	05 Sep 2020 19:52:56

FDA-CBER-2022-1614-2446647

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Protocol Version

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Amendment 2 (2)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

FDA-CBER-2022-1614-2446648

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Was participant enrolled in the study?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

FDA-CBER-2022-1614-2446651

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Was this participant screened previously?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:52:56

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
If Yes, previous participant number

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 18:40:43

FDA-CBER-2022-1614-2446653

US3492078
Folder: Screening
Form: Enrollment
Generated On: 10 Jun 2021 07:56:52
Enrollment Trigger

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1'	System	05 Sep 2020 19:53:14

US3492078
Folder: Screening
Form: Inclusion/Exclusion Criteria Summary
Generated On: 10 Jun 2021 07:56:52
Did the participant meet all eligibility criteria?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:53:14

US3492078
Folder: Screening
Form: Medical History Summary
Generated On: 10 Jun 2021 07:56:52
Were any significant conditions reported?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:53:42

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:26:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:26:33
Data point term sent to Coder	System	13 Nov 2020 21:09:52
User closed query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)CORONARY ARTERY DISEASE 2)CORONARY ARTERY BYPASS GRAFT' (Site from System).	System	13 Nov 2020 21:09:04
Query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)CORONARY ARTERY DISEASE 2)CORONARY ARTERY BYPASS GRAFT' answered with 'done' (Site from System).	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:04
User entered 'CORONARY ARTERY DISEASE' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:08:54
User opened query 'CDM-Coding: For coding purpose,Please split the term to two terms and record separately as; 1)CORONARY ARTERY DISEASE 2)CORONARY ARTERY BYPASS GRAFT' (Site from System).	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:46:46
Data point term sent to Coder	System	04 Nov 2020 20:15:50
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:15:29
User entered 'CORONARY ARTERY DISEASE with coronary artery bypass graft' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:15:29
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 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:03:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:03:37

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data point term sent to Coder	System	05 Sep 2020 20:02:46
User entered 'Coronary artery disease'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2003'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446660

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446661

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446663

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2003'	System	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446664

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2003'	System	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446665

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446666

US3492078
Folder: Screening
Form: Medical History (1)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:02:11

FDA-CBER-2022-1614-2446667

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:04:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:04:37
Data point term sent to Coder	System	05 Sep 2020 20:03:49
User entered 'Atrial fibrillation'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2015'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

FDA-CBER-2022-1614-2446672

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:03:13

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2015'	System	05 Sep 2020 20:03:13

FDA-CBER-2022-1614-2446674

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2015'	System	05 Sep 2020 20:03:13

FDA-CBER-2022-1614-2446675

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:03:13

FDA-CBER-2022-1614-2446676

US3492078
Folder: Screening
Form: Medical History (2)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:03:13

FDA-CBER-2022-1614-2446677

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:05:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:05:37
Data point term sent to Coder	System	05 Sep 2020 20:04:49
User entered 'Congestive heart failure'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2015'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

FDA-CBER-2022-1614-2446680

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

FDA-CBER-2022-1614-2446682

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:04:03

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2015'	System	05 Sep 2020 20:04:03

FDA-CBER-2022-1614-2446684

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2015'	System	05 Sep 2020 20:04:03

FDA-CBER-2022-1614-2446685

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:04:03

FDA-CBER-2022-1614-2446686

US3492078
Folder: Screening
Form: Medical History (3)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:04:03

FDA-CBER-2022-1614-2446687

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
Data point term sent to Coder	System	23 Nov 2020 15:09:56
User coded data point as SOC: Surgical and medical procedures, HLGT: Male genital tract therapeutic procedures, HLT: Prostatic therapeutic procedures, PT: Prostatectomy, LLT: Prostatectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:09:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:09:53
User closed query ' DM-Coding: please split this term into 2 separate entries. One record per line. 1)PROSTATE CANCER 2)PROSTATECTOMY [FOR PROSTATE CANCER]. Please update this term in accordance with your answer.' (Site from System).	System	23 Nov 2020 15:08:56
Query ' DM-Coding: please split this term into 2 separate entries. One record per line. 1)PROSTATE CANCER 2)PROSTATECTOMY [FOR PROSTATE CANCER]. Please update this term in accordance with your answer.' answered with 'will split into two separate entries' (Site from System).	(b) (4), (b) (6)	23 Nov 2020 15:08:56
Data point term sent to Coder	System	23 Nov 2020 15:08:54
User entered 'PROSTATECTOMY' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Nov 2020 15:08:27
User opened query ' DM-Coding: please split this term into 2 separate entries. One record per line. 1)PROSTATE CANCER 2)PROSTATECTOMY [FOR PROSTATE CANCER]. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4) (b) (4)	23 Nov 2020 14:26:51
Data point term sent to Coder	System	04 Nov 2020 20:16:51

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:16:22
User entered 'prostatectomy for PROSTATE CANCER' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:16:22
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:06:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:06:38
Data point term sent to Coder	System	05 Sep 2020 20:05:50
User entered 'Prostate cancer'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 1998'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

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US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 1998'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1998'	System	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1998'	System	05 Sep 2020 20:05:19

FDA-CBER-2022-1614-2446696

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1998'	System	05 Sep 2020 20:05:19

US3492078
Folder: Screening
Form: Medical History (4)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1998'	System	05 Sep 2020 20:05:19

FDA-CBER-2022-1614-2446698

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Renal and urinary tract therapeutic procedures, HLT: Renal therapeutic procedures, PT: Nephrectomy, LLT: Nephrectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:09:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 14:09:46
Data point term sent to Coder	System	04 Nov 2020 20:17:54
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:17:17
User entered 'left nephrectomy for KIDNEY CANCER' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:17:17
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Renal and urinary tract neoplasms malignant and unspecified, HLT: Renal neoplasms malignant, PT: Renal cancer, LLT: Kidney cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:07:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:07:38
Data point term sent to Coder	System	05 Sep 2020 20:06:51
User entered 'Kidney cancer'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2013'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

FDA-CBER-2022-1614-2446701

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

FDA-CBER-2022-1614-2446702

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2013'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:06:17

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2013'	System	05 Sep 2020 20:06:17

FDA-CBER-2022-1614-2446705

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2013'	System	05 Sep 2020 20:06:17

FDA-CBER-2022-1614-2446706

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2013'	System	05 Sep 2020 20:06:17

FDA-CBER-2022-1614-2446707

US3492078
Folder: Screening
Form: Medical History (5)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2013'	System	05 Sep 2020 20:06:17

FDA-CBER-2022-1614-2446708

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Skin and subcutaneous tissue therapeutic procedures, HLT: Skin lesion excisions, PT: Skin neoplasm excision, LLT: Basal cell carcinoma excision - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:32
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 14:32:32
Data point term sent to Coder	System	04 Nov 2020 20:18:58
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:18:39
User entered 's/p resection of BASAL CELL CANCER' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:18:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:08:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:08:38
Data point term sent to Coder	System	05 Sep 2020 20:07:54
User entered 'Basal cell cancer'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

FDA-CBER-2022-1614-2446711

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:07:17

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2018'	System	05 Sep 2020 20:07:17

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2018'	System	05 Sep 2020 20:07:17

FDA-CBER-2022-1614-2446716

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2018'	System	05 Sep 2020 20:07:17

FDA-CBER-2022-1614-2446717

US3492078
Folder: Screening
Form: Medical History (6)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2018'	System	05 Sep 2020 20:07:17

FDA-CBER-2022-1614-2446718

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
Data point term sent to Coder	System	05 Sep 2020 20:08:55
User entered 'S/P CVA'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

FDA-CBER-2022-1614-2446719

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2015'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

FDA-CBER-2022-1614-2446721

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:17:39
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:08:53
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2015' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:17:39
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

FDA-CBER-2022-1614-2446723

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:08:53

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2015'	System	05 Sep 2020 20:08:53

FDA-CBER-2022-1614-2446725

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2015'	System	05 Sep 2020 20:08:53

FDA-CBER-2022-1614-2446726

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2015'	System	05 Sep 2020 20:17:39
User entered empty.	System	05 Sep 2020 20:08:53

US3492078
Folder: Screening
Form: Medical History (7)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2015'	System	05 Sep 2020 20:17:39
User entered empty.	System	05 Sep 2020 20:08:53

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 06:02:50
Data point term sent to Coder	System	05 Sep 2020 20:09:56
User entered 'S/P CVA'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2017'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

FDA-CBER-2022-1614-2446731

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:10:23
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	05 Sep 2020 20:09:33
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2017' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:10:23
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:09:33

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2017'	System	05 Sep 2020 20:09:33

FDA-CBER-2022-1614-2446735

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2017'	System	05 Sep 2020 20:09:33

FDA-CBER-2022-1614-2446736

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2017'	System	05 Sep 2020 20:10:23
User entered empty.	System	05 Sep 2020 20:09:33

FDA-CBER-2022-1614-2446737

US3492078
Folder: Screening
Form: Medical History (8)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2017'	System	05 Sep 2020 20:10:23
User entered empty.	System	05 Sep 2020 20:09:33

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Cerebrovascular accident, LLT: CVA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:45:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Sep 2020 10:45:57
Data point term sent to Coder	System	05 Sep 2020 20:31:17
User entered 'S/P CVA with residual right lower extremity weakness and ataxia' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:31:11
Data point term sent to Coder	System	05 Sep 2020 20:11:58
User entered 'S/P CVA'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2019'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

FDA-CBER-2022-1614-2446741

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Sep 2020 20:35:07
User opened query 'Ongoing is reported as Yes, but Stop Date is provided or Stop date completely unknown is checked. Please correct.' (Site from System).	System	05 Sep 2020 20:34:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:34:05
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

FDA-CBER-2022-1614-2446742

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:35:07
User entered 'UN UNK 2019'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:11:41

FDA-CBER-2022-1614-2446744

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2019'	System	05 Sep 2020 20:11:41

FDA-CBER-2022-1614-2446745

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2019'	System	05 Sep 2020 20:11:41

FDA-CBER-2022-1614-2446746

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:35:07
User entered 'Jan 2019'	System	05 Sep 2020 20:11:41

US3492078
Folder: Screening
Form: Medical History (9)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	05 Sep 2020 20:35:07
User entered '2019'	System	05 Sep 2020 20:11:41

FDA-CBER-2022-1614-2446748

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:41:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Sep 2020 14:41:49
Data point term sent to Coder	System	08 Sep 2020 14:40:53
User entered 'Depression'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2017'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

FDA-CBER-2022-1614-2446751

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

FDA-CBER-2022-1614-2446752

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:40:43

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2017'	System	08 Sep 2020 14:40:43

FDA-CBER-2022-1614-2446755

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2017'	System	08 Sep 2020 14:40:43

FDA-CBER-2022-1614-2446756

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	08 Sep 2020 14:40:43

US3492078
Folder: Screening
Form: Medical History (10)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	08 Sep 2020 14:40:43

FDA-CBER-2022-1614-2446758

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:28:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:28:39
Data point term sent to Coder	System	23 Oct 2020 21:27:25
User entered 'hyperlipidemia'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2003' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	09 Nov 2020 19:33:31
User entered 'un UNK 2005'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2003'	System	09 Nov 2020 19:33:31
User entered 'Jan 2005'	System	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2003'	System	09 Nov 2020 19:33:31
User entered '2005'	System	23 Oct 2020 21:26:50

FDA-CBER-2022-1614-2446766

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	23 Oct 2020 21:26:50

US3492078
Folder: Screening
Form: Medical History (11)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	23 Oct 2020 21:26:50

FDA-CBER-2022-1614-2446768

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:11:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:11:34
Data point term sent to Coder	System	13 Nov 2020 21:10:54
User closed query ' DM-Coding: please split this term into 2 separate entries. 1)TONSILLITIS 2)TONSILLECTOMY . One record per line. Please update this term in accordance with your answer.' (Site from System).	System	13 Nov 2020 21:10:50
Query ' DM-Coding: please split this term into 2 separate entries. 1)TONSILLITIS 2)TONSILLECTOMY . One record per line. Please update this term in accordance with your answer.' answered with 'done' (Site from System).	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:10:50
User entered 'TONSILLITIS' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:10:41
User opened query ' DM-Coding: please split this term into 2 separate entries. 1)TONSILLITIS 2)TONSILLECTOMY . One record per line. Please update this term in accordance with your answer.' (Site from System).	Coder Import (b) (4) (b) (4)	12 Nov 2020 12:06:45
Data point term sent to Coder	System	04 Nov 2020 20:21:01
User entered 's/p tonsillectomy for tonsillitis'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 1932'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

FDA-CBER-2022-1614-2446771

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 1932'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:20:57

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1932'	System	04 Nov 2020 20:20:57

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1932'	System	04 Nov 2020 20:20:57

FDA-CBER-2022-1614-2446776

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1932'	System	04 Nov 2020 20:20:57

FDA-CBER-2022-1614-2446777

US3492078
Folder: Screening
Form: Medical History (12)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1932'	System	04 Nov 2020 20:20:57

FDA-CBER-2022-1614-2446778

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Cardiac arrest, LLT: Cardiac arrest - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 12:28:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Nov 2020 12:28:45
Data point term sent to Coder	System	04 Nov 2020 20:24:05
User entered 's/p cardiac arrest with resuscitation'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 1973'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

FDA-CBER-2022-1614-2446781

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

FDA-CBER-2022-1614-2446782

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 1973'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:24:01

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1973'	System	04 Nov 2020 20:24:01

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1973'	System	04 Nov 2020 20:24:01

FDA-CBER-2022-1614-2446786

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1973'	System	04 Nov 2020 20:24:01

US3492078
Folder: Screening
Form: Medical History (13)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1973'	System	04 Nov 2020 20:24:01

FDA-CBER-2022-1614-2446788

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:27
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:22:27
Data point term sent to Coder	System	06 Nov 2020 21:59:08
User entered 'Right lower extremity edema'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2003'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

FDA-CBER-2022-1614-2446790

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

FDA-CBER-2022-1614-2446791

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

FDA-CBER-2022-1614-2446792

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:59:03

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2003'	System	06 Nov 2020 21:59:03

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2003'	System	06 Nov 2020 21:59:03

FDA-CBER-2022-1614-2446796

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	06 Nov 2020 21:59:03

FDA-CBER-2022-1614-2446797

US3492078
Folder: Screening
Form: Medical History (14)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered empty.	System	06 Nov 2020 21:59:03

FDA-CBER-2022-1614-2446798

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Vascular therapeutic procedures, HLT: Arterial therapeutic procedures (excl aortic), PT: Coronary artery bypass, LLT: Coronary artery bypass graft - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:10:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:10:46
Data point term sent to Coder	System	13 Nov 2020 21:09:53
User entered 'CORONARY ARTERY BYPASS GRAFT'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 2003'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 2003'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2003'	System	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2003'	System	13 Nov 2020 21:09:41

FDA-CBER-2022-1614-2446806

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 2003'	System	13 Nov 2020 21:09:41

US3492078
Folder: Screening
Form: Medical History (15)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '2003'	System	13 Nov 2020 21:09:41

FDA-CBER-2022-1614-2446808

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:12:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 21:12:34
Data point term sent to Coder	System	13 Nov 2020 21:11:59
User entered 'TONSILLECTOMY'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 1932'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 21:12:11
User opened query 'Ongoing is reported as No, but Stop Date is missing and Stop Date completely unknown is not checked. Please provide.' (Site from System).	System	13 Nov 2020 21:11:30
User entered 'No (N)'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'un UNK 1932' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:12:11
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1932'	System	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1932'	System	13 Nov 2020 21:11:30

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US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1932'	System	13 Nov 2020 21:12:11
User entered empty.	System	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (16)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1932'	System	13 Nov 2020 21:12:11
User entered empty.	System	13 Nov 2020 21:11:30

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms male malignant and unspecified, HLT: Prostatic neoplasms malignant, PT: Prostate cancer, LLT: Prostate cancer - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 15:10:55
Data point term sent to Coder	System	23 Nov 2020 15:09:55
User entered 'PROSTATE CANCER'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 1998'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Condition ongoing at study entry

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

FDA-CBER-2022-1614-2446822

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 1998'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Stop date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	(b) (4), (b) (6)	23 Nov 2020 15:09:43

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1998'	System	23 Nov 2020 15:09:43

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1998'	System	23 Nov 2020 15:09:43

FDA-CBER-2022-1614-2446826

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Stop Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'Jan 1998'	System	23 Nov 2020 15:09:43

FDA-CBER-2022-1614-2446827

US3492078
Folder: Screening
Form: Medical History (17)
Generated On: 10 Jun 2021 07:56:52
Stop Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '1998'	System	23 Nov 2020 15:09:43

FDA-CBER-2022-1614-2446828

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '13:49'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '5 Sep 2020 13:49'	System	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Height *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '187.9' cm	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59
DataPoint set to visible.	System	05 Sep 2020 19:53:14

FDA-CBER-2022-1614-2446833

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Weight *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '82.5' kg	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59
DataPoint set to visible.	System	05 Sep 2020 19:53:14

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
BMI *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered '23.36686'	System	05 Sep 2020 19:57:59
DataPoint set to visible.	System	05 Sep 2020 19:53:14

FDA-CBER-2022-1614-2446835

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
BMI units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'kg/m2'	System	05 Sep 2020 19:57:59
DataPoint set to visible.	System	05 Sep 2020 19:53:14

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:43
Query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:24
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:00
User opened query 'Per CDM: Per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening if Visit 1 Day 1 and Screening occurred on the same day. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:34:58
User entered '36.8' C	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:00
User entered 'Other (Other)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:00
User entered 'Tympanic'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:00
User entered '58'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'bpm'	System	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446841

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:00
User entered '20'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446842

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'breaths/min'	System	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446843

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:17
User entered '148'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446844

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'mmHg'	System	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446845

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:17
User entered '74'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446846

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User entered 'mmHg'	System	05 Sep 2020 19:57:59

FDA-CBER-2022-1614-2446847

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38

FDA-CBER-2022-1614-2446848

US3492078
Folder: Screening
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38

FDA-CBER-2022-1614-2446849

US3492078
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:58:14

US3492078
Folder: Screening
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:58:14

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

FDA-CBER-2022-1614-2446852

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

FDA-CBER-2022-1614-2446856

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:00:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:00:03
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:00:03
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 19:59:51
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

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US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

FDA-CBER-2022-1614-2446866

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

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US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
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)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Resides in a single family home (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '1'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

FDA-CBER-2022-1614-2446870

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

FDA-CBER-2022-1614-2446871

US3492078
Folder: Screening
Form: Risk of Exposure
Generated On: 10 Jun 2021 07:56:52
Specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:25:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 19:59:51

FDA-CBER-2022-1614-2446872

US3492078
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:12:33

US3492078
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:12:33

US3492078
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Clinic (Clinic)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:12:33

US3492078
Folder: Visit 1 Day 1
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'VISIT1'	System	05 Sep 2020 20:12:33

FDA-CBER-2022-1614-2446876

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
What was the date of randomization? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '05 SEP 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 19:50:43

FDA-CBER-2022-1614-2446877

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '190151'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 19:50:43

FDA-CBER-2022-1614-2446878

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
In what Cohort was the participant enrolled?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	05 Sep 2020 19:50:43

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52

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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

FDA-CBER-2022-1614-2446881

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

FDA-CBER-2022-1614-2446883

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
Liver Disease

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:13:25

FDA-CBER-2022-1614-2446884

US3492078
Folder: Visit 1 Day 1
Form: Randomization
Generated On: 10 Jun 2021 07:56:52
Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:07:44
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:33:18

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 07:56:52
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:36
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 accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:59:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:57
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:35:06
User entered '187.9' cm	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

FDA-CBER-2022-1614-2446886

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 07:56:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:59:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:59:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:58:57
User entered 'kg' (non-conformant).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:57
User entered '82.5' kg	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 07:56:52
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:36
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 accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:59:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:57
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:35:06
User entered '187.9' cm	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 07:56:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:59:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:59:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:58:57
User entered 'kg' (non-conformant).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:57
User entered '82.5' kg	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Pre-Dose (PREDOSE)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '14:49'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '5 Sep 2020 14:49'	System	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 14:47:03
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4) (b) (4)	17 Sep 2020 17:34:40
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:29:32
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:24:29
User entered '35.6' C reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Other (Other)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Tympanic' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:24:29
User entered '56' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'bpm'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:24:29
User entered '20' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'breaths/min'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 15:12:06
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:40
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 21:24:29
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:24:29
User entered '159' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:24:29
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:24:29
User entered '80' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:24:29
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	05 Sep 2020 21:24:29
User entered empty.	System	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 07:56:52
Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 05:28:36
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 accordingly.' answered with 'Corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:59:07
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:57
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 accordingly.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 17:35:06
User entered '187.9' cm	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing
Generated On: 10 Jun 2021 07:56:52
Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:59:47
User entered missing code ND - Not Done; reason for change Data Entry Error	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:59:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	22 Sep 2020 00:58:57
User entered 'kg' (non-conformant).	Marla Schwarber (b) (4) (b) (4)	22 Sep 2020 00:58:57
User entered '82.5' kg	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Post-Dose (POSTDOSE)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 21:23:18
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 21:23:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:23:18
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:14:17
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '16:15' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

FDA-CBER-2022-1614-2446911

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '5 Sep 2020 16:15'	System	05 Sep 2020 21:23:18
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 14:47:08
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4) (b) (4)	17 Sep 2020 17:35:02
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:29:32
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '35.6' C reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Other (Other)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Tympanic' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '56' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'bpm'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '20' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'breaths/min'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 15:12:13
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:48
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	05 Sep 2020 21:29:34
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '159' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:29:34
Query 'Data is required. Please provide.' answered by data change (Site from System).	System	05 Sep 2020 21:29:34
User entered '80' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 21:29:34
User opened query 'Data is required. Please provide.' (Site from System).	System	05 Sep 2020 21:23:18
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:17

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US3492078
Folder: Visit 1 Day 1
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	05 Sep 2020 21:29:34
User entered empty.	System	05 Sep 2020 20:14:17

US3492078
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:36

US3492078
Folder: Visit 1 Day 1
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:14:36

FDA-CBER-2022-1614-2446925

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446926

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446927

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446929

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446930

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15:59'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446931

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '5 Sep 2020 15:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Left Arm (LEFT ARM)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446933

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'ONCE'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446934

US3492078
Folder: Visit 1 Day 1
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446935

US3492078
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:26

FDA-CBER-2022-1614-2446936

US3492078
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:26

FDA-CBER-2022-1614-2446937

US3492078
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '14:29'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:26

FDA-CBER-2022-1614-2446938

US3492078
Folder: Visit 1 Day 1
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '5 Sep 2020 14:29'	System	05 Sep 2020 20:18:26

FDA-CBER-2022-1614-2446939

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5 Sep 2020'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

FDA-CBER-2022-1614-2446942

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '14:15'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

FDA-CBER-2022-1614-2446943

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '5 Sep 2020 14:15'	System	05 Sep 2020 20:18:59

FDA-CBER-2022-1614-2446944

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:19:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	05 Sep 2020 20:19:13
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:19:13
User opened query 'Data is required. Please complete.' (Site from System).	System	05 Sep 2020 20:18:59
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:18:59

FDA-CBER-2022-1614-2446947

US3492078
Folder: Visit 1 Day 1
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered empty.	System	05 Sep 2020 20:18:59

US3492078
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:37:36

FDA-CBER-2022-1614-2446949

US3492078
Folder: Visit 1 Day 1
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	08 Sep 2020 14:37:36

FDA-CBER-2022-1614-2446950

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446952

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446954

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446955

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446956

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446957

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 16:19'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446958

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 18:49'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446959

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446961

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446962

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446964

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446965

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446966

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 19:44'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446967

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446968

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 2'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446970

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446971

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446972

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446973

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446974

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446975

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446976

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446977

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 3'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446979

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446980

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446981

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446982

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446983

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446984

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446985

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446986

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 4'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446988

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446989

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446990

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446991

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446992

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446993

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446994

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2446995

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 5'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446997

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2446998

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447002

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447003

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447004

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 6'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447006

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447007

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447009

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447011

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447012

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447013

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 7'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447015

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447016

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447017

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447018

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447019

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447020

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447021

US3492078
Folder: Diary Dose 1 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447022

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447024

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447025

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447026

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447027

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447028

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447030

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 16:19'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447031

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 18:49'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447032

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447035

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447036

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447037

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447038

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447040

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 19:44'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447041

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447042

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 2'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447044

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447045

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447046

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447047

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447048

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447050

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447051

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447052

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 3'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447054

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447055

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447056

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447057

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447058

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447060

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447061

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447062

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 4'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447064

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447065

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447066

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447067

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447068

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447070

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447071

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447072

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 5'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447074

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447075

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447076

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447077

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447078

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447080

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447081

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447082

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 6'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447084

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447087

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447088

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447090

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447091

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447092

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 7'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447094

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447097

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

FDA-CBER-2022-1614-2447098

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447100

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447101

US3492078
Folder: Diary Dose 1 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447102

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447104

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447105

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447107

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447108

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447109

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447111

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 16:19'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 18:49'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447113

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447115

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447116

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447117

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447118

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447119

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447120

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447122

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Sep 2020 19:44'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447124

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 2'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447126

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447127

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447128

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447129

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447130

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447131

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447133

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 3'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447137

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447138

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447139

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447140

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447141

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447142

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447144

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447146

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 4'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447148

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447149

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447150

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447151

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447152

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447153

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447155

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447157

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 5'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447159

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447160

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447161

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447162

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447163

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447164

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447166

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447167

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 6'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447169

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447170

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447171

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447172

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447173

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447174

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447175

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447177

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447178

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

FDA-CBER-2022-1614-2447179

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 7'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447181

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447182

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447183

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447185

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447186

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04

FDA-CBER-2022-1614-2447188

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 15:10:36

US3492078
Folder: Diary Dose 1 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

US3492078
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '14 Sep 2020'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

US3492078
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

FDA-CBER-2022-1614-2447193

US3492078
Folder: Safety Call Day 8 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:26

FDA-CBER-2022-1614-2447194

US3492078
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	14 Sep 2020 19:50:30

US3492078
Folder: Safety Call Day 8 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	14 Sep 2020 19:50:30

FDA-CBER-2022-1614-2447196

US3492078
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

US3492078
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '21 Sep 2020'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

FDA-CBER-2022-1614-2447198

US3492078
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

FDA-CBER-2022-1614-2447199

US3492078
Folder: Safety Call Day 15 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:34

US3492078
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	21 Sep 2020 21:00:41

FDA-CBER-2022-1614-2447201

US3492078
Folder: Safety Call Day 15 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	21 Sep 2020 21:00:41

FDA-CBER-2022-1614-2447202

US3492078
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '29 Sep 2020'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

US3492078
Folder: Safety Call Day 22 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:06

FDA-CBER-2022-1614-2447206

US3492078
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Elena Llinas (b) (4) (b) (4)	29 Sep 2020 21:26:09

FDA-CBER-2022-1614-2447207

US3492078
Folder: Safety Call Day 22 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	29 Sep 2020 21:26:09

US3492078
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:07:11

FDA-CBER-2022-1614-2447209

US3492078
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:07:11

FDA-CBER-2022-1614-2447210

US3492078
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Clinic (Clinic)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:07:11

US3492078
Folder: Visit 2 Day 29 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'VISIT2'	System	02 Oct 2020 19:07:11

FDA-CBER-2022-1614-2447212

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Pre-Dose (PREDOSE)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447213

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447215

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '13:24'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '02 Oct 2020 13:24'	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447217

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '97.3' F	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447218

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Other (Other)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'tympanic'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447220

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '60'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447221

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'bpm'	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447222

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '16'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'breaths/min'	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447224

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '165'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447226

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '78'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447227

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (1)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447228

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Timepoint

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Post-Dose (POSTDOSE)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 20:24:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 20:24:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 19:08:13
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '14:55' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '02 Oct 2020 14:55'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '36' C reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Other (Other)' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'tympanic' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '62' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447237

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'bpm'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447238

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '16' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'breaths/min'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447240

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '134' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447241

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447242

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '71' reason for change: Data Entry Error	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:24:07
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447243

US3492078
Folder: Visit 2 Day 29 (1)
Form: Vital Signs - Dosing (2)
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	02 Oct 2020 20:24:07
User entered empty.	System	02 Oct 2020 19:08:13

FDA-CBER-2022-1614-2447244

US3492078
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:36

FDA-CBER-2022-1614-2447245

US3492078
Folder: Visit 2 Day 29 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:36

FDA-CBER-2022-1614-2447246

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
Was study treatment given?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447247

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447249

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'MRNA-1273 OR PLACEBO'	System	02 Oct 2020 20:25:24

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the treatment date? *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447251

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the treatment time? *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '14:53'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447252

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
Treatment Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '02 Oct 2020 14:53'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447253

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Left Arm (LEFT ARM)'	Michelle Agnoli (b) (4) (b) (4)	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447254

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'ONCE'	System	02 Oct 2020 20:25:24

US3492078
Folder: Visit 2 Day 29 (1)
Form: Exposure
Generated On: 10 Jun 2021 07:56:52
What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'INTRAMUSCULAR'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447256

US3492078
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:54

FDA-CBER-2022-1614-2447257

US3492078
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:54

US3492078
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '13:43'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:08:54

FDA-CBER-2022-1614-2447259

US3492078
Folder: Visit 2 Day 29 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '02 Oct 2020 13:43'	System	02 Oct 2020 19:08:54

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '02 Oct 2020'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

FDA-CBER-2022-1614-2447262

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '13:50'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

FDA-CBER-2022-1614-2447264

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (1)
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '02 Oct 2020 13:50'	System	02 Oct 2020 19:09:15

FDA-CBER-2022-1614-2447265

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Lab Test

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:15

US3492078
Folder: Visit 2 Day 29 (1)
Form: Central Laboratory - Nasopharyngeal Swab (2)
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered empty.	System	02 Oct 2020 19:09:15

US3492078
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Diana Bahena (b) (4) (b) (4)	02 Oct 2020 19:09:20

FDA-CBER-2022-1614-2447270

US3492078
Folder: Visit 2 Day 29 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	02 Oct 2020 19:09:20

FDA-CBER-2022-1614-2447271

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447272

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:30:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered 'Yes (Y)'	System	03 Oct 2020 17:02:37

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:30:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered '96.8'	System	03 Oct 2020 17:02:37

FDA-CBER-2022-1614-2447274

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:31:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered 'No (N)'	System	03 Oct 2020 17:02:37

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:08', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd76295b1-8028-4e9d-8a04-61eb531bc504'	System	03 Oct 2020 17:02:37
User entered '02 Oct 2020 15:32'	System	03 Oct 2020 17:02:37

FDA-CBER-2022-1614-2447276

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 15:13'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447277

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 17:43'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447278

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd'	System	03 Oct 2020 17:02:42
User entered 'Yes (Y)'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447280

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd'	System	03 Oct 2020 17:02:42
User entered '97.9'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447281

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:32', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd'	System	03 Oct 2020 17:02:42
User entered 'No (N)'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447282

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:35', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '472f2ec1-4555-493c-9fea-7c3312c723bd'	System	03 Oct 2020 17:02:42
User entered '02 Oct 2020 18:39'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447283

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 18:38'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447284

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

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US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 2'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447286

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered 'Yes (Y)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447287

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered '98.1'	System	03 Oct 2020 17:02:44

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US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered 'No (N)'	System	03 Oct 2020 17:02:44

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US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:39', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '76d695f3-9084-4708-bd44-ee5bcfb32d93'	System	03 Oct 2020 17:02:44
User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447290

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447291

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447292

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 3'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447293

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered 'Yes (Y)'	System	04 Oct 2020 18:10:41

FDA-CBER-2022-1614-2447294

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered '98.0'	System	04 Oct 2020 18:10:41

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:35', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered 'No (N)'	System	04 Oct 2020 18:10:41

FDA-CBER-2022-1614-2447296

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'a2802828-760f-41f3-a7f3-8738056948ee'	System	04 Oct 2020 18:10:41
User entered '04 Oct 2020 13:10'	System	04 Oct 2020 18:10:41

FDA-CBER-2022-1614-2447297

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447298

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447299

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 4'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered 'Yes (Y)'	System	05 Oct 2020 21:14:18

FDA-CBER-2022-1614-2447301

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:11', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered '97.9'	System	05 Oct 2020 21:14:18

FDA-CBER-2022-1614-2447302

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered 'No (N)'	System	05 Oct 2020 21:14:18

FDA-CBER-2022-1614-2447303

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:16', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2c33fc1-cbda-4896-9d47-5c5680d0c1ac'	System	05 Oct 2020 21:14:18
User entered '05 Oct 2020 16:14'	System	05 Oct 2020 21:14:18

FDA-CBER-2022-1614-2447304

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447305

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447306

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 5'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447307

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered 'Yes (Y)'	System	06 Oct 2020 23:49:26

FDA-CBER-2022-1614-2447308

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:20', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered '98.0'	System	06 Oct 2020 23:49:26

FDA-CBER-2022-1614-2447309

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered 'No (N)'	System	06 Oct 2020 23:49:26

FDA-CBER-2022-1614-2447310

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f8a2c1a7-2d91-460c-a660-030100127d70'	System	06 Oct 2020 23:49:26
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:26

FDA-CBER-2022-1614-2447311

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447312

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447313

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 6'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447314

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:50:57', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered 'Yes (Y)'	System	08 Oct 2020 01:51:08

FDA-CBER-2022-1614-2447315

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered '97.7'	System	08 Oct 2020 01:51:08

FDA-CBER-2022-1614-2447316

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered 'No (N)'	System	08 Oct 2020 01:51:08

FDA-CBER-2022-1614-2447317

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:06', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '791036a3-a496-4de2-9cc8-553b0123b062'	System	08 Oct 2020 01:51:08
User entered '07 Oct 2020 20:51'	System	08 Oct 2020 01:51:08

FDA-CBER-2022-1614-2447318

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447319

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447320

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 7'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447321

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d'	System	08 Oct 2020 23:45:20
User entered 'Yes (Y)'	System	08 Oct 2020 23:45:20

FDA-CBER-2022-1614-2447322

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d'	System	08 Oct 2020 23:45:20
User entered '98.1'	System	08 Oct 2020 23:45:20

FDA-CBER-2022-1614-2447323

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
Was any **MEDICATION TAKEN today for pain or fever**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d'	System	08 Oct 2020 23:45:20
User entered 'No (N)'	System	08 Oct 2020 23:45:20

FDA-CBER-2022-1614-2447324

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:17', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '19e3f236-bada-4065-b6f0-b25b1fff164d'	System	08 Oct 2020 23:45:20
User entered '08 Oct 2020 18:45'	System	08 Oct 2020 23:45:20

FDA-CBER-2022-1614-2447325

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447326

US3492078
Folder: Diary Dose 2 (1)
Form: Temperature_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447327

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'None (1)'	System	03 Oct 2020 17:02:38

FDA-CBER-2022-1614-2447329

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:18', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'No (N)'	System	03 Oct 2020 17:02:38

FDA-CBER-2022-1614-2447330

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:23', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'No (N)'	System	03 Oct 2020 17:02:38

FDA-CBER-2022-1614-2447331

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:29', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered 'None (1)'	System	03 Oct 2020 17:02:38

FDA-CBER-2022-1614-2447332

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:32:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0ab86b09-b137-41b4-b8f6-9ec500bf1511'	System	03 Oct 2020 17:02:38
User entered '02 Oct 2020 15:32'	System	03 Oct 2020 17:02:38

FDA-CBER-2022-1614-2447333

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 15:13'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447334

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 17:43'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447335

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:41', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'Does not interfere with activity (2)'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447337

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'No (N)'	System	03 Oct 2020 17:02:42

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:44', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'No (N)'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447339

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered 'None (1)'	System	03 Oct 2020 17:02:42

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f911910e-34c5-4d19-ba5f-109e77631f1e'	System	03 Oct 2020 17:02:42
User entered '02 Oct 2020 18:39'	System	03 Oct 2020 17:02:42

FDA-CBER-2022-1614-2447341

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 18:38'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447342

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447343

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 2'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447344

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'None (1)'	System	03 Oct 2020 17:02:52

FDA-CBER-2022-1614-2447345

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:44', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'No (N)'	System	03 Oct 2020 17:02:52

FDA-CBER-2022-1614-2447346

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'No (N)'	System	03 Oct 2020 17:02:52

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered 'None (1)'	System	03 Oct 2020 17:02:52

FDA-CBER-2022-1614-2447348

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '27a3318e-7360-4f57-95d4-20cba2f752e8'	System	03 Oct 2020 17:02:52
User entered '03 Oct 2020 12:02'	System	03 Oct 2020 17:02:52

FDA-CBER-2022-1614-2447349

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447351

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 3'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447352

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:40', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'None (1)'	System	04 Oct 2020 18:10:49

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'No (N)'	System	04 Oct 2020 18:10:49

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'No (N)'	System	04 Oct 2020 18:10:49

FDA-CBER-2022-1614-2447355

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:45', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered 'None (1)'	System	04 Oct 2020 18:10:49

FDA-CBER-2022-1614-2447356

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:46', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '516491b9-1140-46b8-bbde-619922d37ff7'	System	04 Oct 2020 18:10:49
User entered '04 Oct 2020 13:10'	System	04 Oct 2020 18:10:49

FDA-CBER-2022-1614-2447357

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447358

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447359

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 4'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:20', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'None (1)'	System	05 Oct 2020 21:15:03

FDA-CBER-2022-1614-2447361

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:21', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'No (N)'	System	05 Oct 2020 21:15:03

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'Yes (Y)'	System	05 Oct 2020 21:15:03

FDA-CBER-2022-1614-2447363

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:48', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered '4'	System	05 Oct 2020 21:15:03

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:14:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered 'None (1)'	System	05 Oct 2020 21:15:03

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:01', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2a915d3a-779b-4c23-812d-795445a8174d'	System	05 Oct 2020 21:15:03
User entered '05 Oct 2020 16:15'	System	05 Oct 2020 21:15:03

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447368

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 5'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447369

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:28', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'None (1)'	System	06 Oct 2020 23:49:42

FDA-CBER-2022-1614-2447370

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'No (N)'	System	06 Oct 2020 23:49:42

FDA-CBER-2022-1614-2447371

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:32', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'No (N)'	System	06 Oct 2020 23:49:42

FDA-CBER-2022-1614-2447372

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered 'None (1)'	System	06 Oct 2020 23:49:42

FDA-CBER-2022-1614-2447373

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:36', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '61f2dec3-28fd-4d4b-9620-adc37cf02f50'	System	06 Oct 2020 23:49:42
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:42

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447375

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447376

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 6'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9'	System	08 Oct 2020 01:51:19
User entered 'None (1)'	System	08 Oct 2020 01:51:19

FDA-CBER-2022-1614-2447378

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:11', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9'	System	08 Oct 2020 01:51:19
User entered 'No (N)'	System	08 Oct 2020 01:51:19

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:12', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9'	System	08 Oct 2020 01:51:19
User entered 'No (N)'	System	08 Oct 2020 01:51:19

FDA-CBER-2022-1614-2447380

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9'	System	08 Oct 2020 01:51:19
User entered 'None (1)'	System	08 Oct 2020 01:51:19

FDA-CBER-2022-1614-2447381

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:16', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '25e75d1a-a291-4313-af8b-261615d104e9'	System	08 Oct 2020 01:51:19
User entered '07 Oct 2020 20:51'	System	08 Oct 2020 01:51:19

FDA-CBER-2022-1614-2447382

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447383

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447384

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 7'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447385

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:20', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'None (1)'	System	08 Oct 2020 23:45:30

FDA-CBER-2022-1614-2447386

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
Is there any **REDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'No (N)'	System	08 Oct 2020 23:45:30

FDA-CBER-2022-1614-2447387

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
Is there any **SWELLING/HARDNESS AT INJECTION SITE**?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'No (N)'	System	08 Oct 2020 23:45:30

FDA-CBER-2022-1614-2447388

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:25', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered 'None (1)'	System	08 Oct 2020 23:45:30

FDA-CBER-2022-1614-2447389

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Time Stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:27', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'd2b640a4-3fe1-4c99-a030-9e816aae0966'	System	08 Oct 2020 23:45:30
User entered '08 Oct 2020 18:45'	System	08 Oct 2020 23:45:30

FDA-CBER-2022-1614-2447390

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447391

US3492078
Folder: Diary Dose 2 (1)
Form: Injection Site_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447392

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447393

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

FDA-CBER-2022-1614-2447394

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:14', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

FDA-CBER-2022-1614-2447395

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

FDA-CBER-2022-1614-2447396

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:29', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

FDA-CBER-2022-1614-2447397

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

FDA-CBER-2022-1614-2447398

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'None (0)'	System	03 Oct 2020 17:02:40

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered 'No (N)'	System	03 Oct 2020 17:02:40

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T15:33:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '0bf80edb-230d-4f1a-8465-1eeaa99f933a'	System	03 Oct 2020 17:02:40
User entered '02 Oct 2020 15:33'	System	03 Oct 2020 17:02:40

FDA-CBER-2022-1614-2447401

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 15:13'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447402

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/1)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 17:43'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447403

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 1, after vaccination (at home)'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447405

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447406

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447407

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:55', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447408

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:56', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447409

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:39:58', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'None (0)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447410

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:40:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered 'No (N)'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447411

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-02T18:40:02', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8dbfac0e-d694-4a6e-9ac4-24c4168b3617'	System	03 Oct 2020 17:02:44
User entered '02 Oct 2020 18:40'	System	03 Oct 2020 17:02:44

FDA-CBER-2022-1614-2447412

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '02 Oct 2020 18:38'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447413

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(1/2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '03 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447414

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 2'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'None (0)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447416

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:54', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'None (0)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447417

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:55', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'None (0)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447418

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:57', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'None (0)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447419

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:02:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'None (0)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447420

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:03:01', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'None (0)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447421

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:03:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered 'No (N)'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447422

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-03T12:03:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f68dba7c-56ed-4694-99ee-6da81d72d8eb'	System	03 Oct 2020 17:03:07
User entered '03 Oct 2020 12:03'	System	03 Oct 2020 17:03:07

FDA-CBER-2022-1614-2447423

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '03 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447424

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(2)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '04 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447425

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 3'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447426

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447427

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:51', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447428

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447429

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447430

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:54', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447431

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:55', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'None (0)'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447432

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:56', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered 'No (N)'	System	04 Oct 2020 18:11:01

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-04T13:10:58', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '77c7d4b1-beb3-4320-97d4-a1b0b73f65b3'	System	04 Oct 2020 18:11:01
User entered '04 Oct 2020 13:10'	System	04 Oct 2020 18:11:01

FDA-CBER-2022-1614-2447434

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '04 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447435

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(3)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447436

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 4'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447437

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447438

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447439

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:06', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447440

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:08', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447441

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447442

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:11', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'None (0)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447443

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:12', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered 'No (N)'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447444

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-05T16:15:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f976334-6802-40ba-a53b-c49e0acc7380'	System	05 Oct 2020 21:15:18
User entered '05 Oct 2020 16:15'	System	05 Oct 2020 21:15:18

FDA-CBER-2022-1614-2447445

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '05 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447446

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(4)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447447

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 5'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447448

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:39', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447449

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:41', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447450

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447451

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:43', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447452

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:44', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447453

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:45', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'None (0)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447454

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered 'No (N)'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447455

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-06T18:49:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '2c3acfda-5db8-4f0e-8759-fce22aa2e0a7'	System	06 Oct 2020 23:49:53
User entered '06 Oct 2020 18:49'	System	06 Oct 2020 23:49:53

FDA-CBER-2022-1614-2447456

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '06 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447457

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(5)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447458

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 6'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447459

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:19', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447460

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:21', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447461

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447462

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:23', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447463

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447464

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'None (0)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447465

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:28', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered 'No (N)'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447466

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-07T20:51:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '890ce06a-db1b-4df1-a8b1-b597084b0bd4'	System	08 Oct 2020 01:51:37
User entered '07 Oct 2020 20:51'	System	08 Oct 2020 01:51:37

FDA-CBER-2022-1614-2447467

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '07 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447468

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(6)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447469

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	02 Oct 2020 20:25:24
User entered 'Day 7'	System	02 Oct 2020 20:25:24

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447471

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:31', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447472

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:32', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447473

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447474

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:35', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447475

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'None (0)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447476

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:38', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered 'No (N)'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447477

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Time stamp

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-10-08T18:45:40', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4d7e9be5-bc77-4dca-996b-53060c495a78'	System	08 Oct 2020 23:45:42
User entered '08 Oct 2020 18:45'	System	08 Oct 2020 23:45:42

FDA-CBER-2022-1614-2447478

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '08 Oct 2020 12:00'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447479

US3492078
Folder: Diary Dose 2 (1)
Form: General_Day(7)
Generated On: 10 Jun 2021 07:56:52
PC Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
User entered '09 Oct 2020 11:59'	System	02 Oct 2020 20:25:24

FDA-CBER-2022-1614-2447480

US3492078
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

FDA-CBER-2022-1614-2447481

US3492078
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '09 Oct 2020'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

FDA-CBER-2022-1614-2447482

US3492078
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

FDA-CBER-2022-1614-2447483

US3492078
Folder: Safety Call Day 36 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:05

FDA-CBER-2022-1614-2447484

US3492078
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:10:12

US3492078
Folder: Safety Call Day 36 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	09 Oct 2020 21:10:12

FDA-CBER-2022-1614-2447486

US3492078
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

US3492078
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '19 Oct 2020'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

US3492078
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

FDA-CBER-2022-1614-2447489

US3492078
Folder: Safety Call Day 43 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:54:40

FDA-CBER-2022-1614-2447490

US3492078
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	19 Oct 2020 15:55:25

FDA-CBER-2022-1614-2447491

US3492078
Folder: Safety Call Day 43 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	19 Oct 2020 15:55:25

FDA-CBER-2022-1614-2447492

US3492078
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

US3492078
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '23 Oct 2020'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

US3492078
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

FDA-CBER-2022-1614-2447495

US3492078
Folder: Safety Call Day 50 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:57:08

FDA-CBER-2022-1614-2447496

US3492078
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	26 Oct 2020 14:56:54

FDA-CBER-2022-1614-2447497

US3492078
Folder: Safety Call Day 50 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	26 Oct 2020 14:56:54

FDA-CBER-2022-1614-2447498

US3492078
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:54:12

FDA-CBER-2022-1614-2447499

US3492078
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:54:12

FDA-CBER-2022-1614-2447500

US3492078
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
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 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	06 Nov 2020 21:54:12

FDA-CBER-2022-1614-2447501

US3492078
Folder: Visit 3 Day 57 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'VISIT3'	System	06 Nov 2020 21:54:12

FDA-CBER-2022-1614-2447502

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447503

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447504

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15:15'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '06 Nov 2020 15:15'	System	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447506

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '37.4' C	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered 'Other (Other)'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447508

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered 'tympanic'	(b) (4), (b) (6) (b) (4)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447509

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '78'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'bpm'	System	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447511

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '20'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447512

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'breaths/min'	System	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447513

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '116'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447514

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447515

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '66'	(b) (4), (b) (6)	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447516

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered 'mmHg'	System	06 Nov 2020 21:54:48

FDA-CBER-2022-1614-2447517

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10

FDA-CBER-2022-1614-2447518

US3492078
Folder: Visit 3 Day 57 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10

FDA-CBER-2022-1614-2447519

US3492078
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:54:56

FDA-CBER-2022-1614-2447520

US3492078
Folder: Visit 3 Day 57 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:54:56

FDA-CBER-2022-1614-2447521

US3492078
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:55:08

FDA-CBER-2022-1614-2447522

US3492078
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '06 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:55:08

FDA-CBER-2022-1614-2447523

US3492078
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '15:26'	(b) (4), (b) (6)	06 Nov 2020 21:55:08

FDA-CBER-2022-1614-2447524

US3492078
Folder: Visit 3 Day 57 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '06 Nov 2020 15:26'	System	06 Nov 2020 21:55:08

US3492078
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:55:12

FDA-CBER-2022-1614-2447526

US3492078
Folder: Visit 3 Day 57 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	06 Nov 2020 21:55:12

FDA-CBER-2022-1614-2447527

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 64'	System	08 Sep 2020 15:10:36

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-08T18:01:07', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '21f48897-eea1-4b88-8213-2635b545bebb'	System	09 Nov 2020 00:01:18
User entered 'No (N)'	System	09 Nov 2020 00:01:18

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-08T18:01:09', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '21f48897-eea1-4b88-8213-2635b545bebb'	System	09 Nov 2020 00:01:18
User entered 'No (N)'	System	09 Nov 2020 00:01:18

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-08T18:01:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '21f48897-eea1-4b88-8213-2635b545bebb'	System	09 Nov 2020 00:01:18
User entered '08 Nov 2020 18:01:13'	System	09 Nov 2020 00:01:18

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '05 Nov 2020 00:01'	System	08 Sep 2020 15:10:36

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 22:16:04
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '09 Nov 2020 23:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 71'	System	08 Sep 2020 15:10:36

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

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US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

FDA-CBER-2022-1614-2447539

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

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US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

FDA-CBER-2022-1614-2447556

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '12 Nov 2020 00:01'	System	08 Sep 2020 15:10:36

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '16 Nov 2020 23:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13
Data entry locked.	System	08 Sep 2020 15:10:36
User entered 'Day 78'	System	08 Sep 2020 15:10:36

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Fever (Temperature ≥ 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Chills

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Cough

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Shortness of breath

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Difficulty breathing

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Fatigue

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

FDA-CBER-2022-1614-2447572

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Muscle aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Body aches

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Headache

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
New loss of taste

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
New loss of smell

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Sore throat

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Congestion

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Runny nose

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Nausea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Vomiting

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Diarrhea

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '19 Nov 2020 00:01'	System	08 Sep 2020 15:10:36

US3492078
Folder: Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 05:47:13
Data entry locked.	System	08 Sep 2020 15:10:36
User entered '23 Nov 2020 23:59'	System	08 Sep 2020 15:10:36

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-25T20:23:08', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8746c71a-ca2b-4ee1-8d11-681cdbf78cef'	System	26 Nov 2020 02:23:16
User entered 'No (N)'	System	26 Nov 2020 02:23:16

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-25T20:23:10', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8746c71a-ca2b-4ee1-8d11-681cdbf78cef'	System	26 Nov 2020 02:23:16
User entered 'No (N)'	System	26 Nov 2020 02:23:16

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-25T20:23:13', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8746c71a-ca2b-4ee1-8d11-681cdbf78cef'	System	26 Nov 2020 02:23:16
User entered '25 Nov 2020 20:23:13'	System	26 Nov 2020 02:23:16

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Nov 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-30T19:14:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4624062b-6282-473f-8b56-b82b076e51ba'	System	01 Dec 2020 01:14:13
User entered 'No (N)'	System	01 Dec 2020 01:14:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-30T19:14:04', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4624062b-6282-473f-8b56-b82b076e51ba'	System	01 Dec 2020 01:14:13
User entered 'No (N)'	System	01 Dec 2020 01:14:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-11-30T19:14:07', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4624062b-6282-473f-8b56-b82b076e51ba'	System	01 Dec 2020 01:14:13
User entered '30 Nov 2020 19:14:07'	System	01 Dec 2020 01:14:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Nov 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-07T17:01:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '39ea41a0-c472-4832-bce4-720955709848'	System	07 Dec 2020 23:02:09
User entered 'No (N)'	System	07 Dec 2020 23:02:09

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-07T17:02:01', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '39ea41a0-c472-4832-bce4-720955709848'	System	07 Dec 2020 23:02:09
User entered 'No (N)'	System	07 Dec 2020 23:02:09

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-07T17:02:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '39ea41a0-c472-4832-bce4-720955709848'	System	07 Dec 2020 23:02:09
User entered '07 Dec 2020 17:02:03'	System	07 Dec 2020 23:02:09

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-14T20:53:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f43bd7bb-3162-4e56-9722-414643cafc8a'	System	15 Dec 2020 02:54:07
User entered 'No (N)'	System	15 Dec 2020 02:54:07

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-14T20:54:02', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f43bd7bb-3162-4e56-9722-414643cafc8a'	System	15 Dec 2020 02:54:07
User entered 'No (N)'	System	15 Dec 2020 02:54:07

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-14T20:54:05', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'f43bd7bb-3162-4e56-9722-414643cafc8a'	System	15 Dec 2020 02:54:07
User entered '14 Dec 2020 20:54:05'	System	15 Dec 2020 02:54:07

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-21T00:03:07', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'fd6f9519-7616-422b-8bdb-b16c589484c9'	System	21 Dec 2020 06:03:20
User entered 'No (N)'	System	21 Dec 2020 06:03:20

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-21T00:03:10', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'fd6f9519-7616-422b-8bdb-b16c589484c9'	System	21 Dec 2020 06:03:20
User entered 'No (N)'	System	21 Dec 2020 06:03:20

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-21T00:03:15', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'fd6f9519-7616-422b-8bdb-b16c589484c9'	System	21 Dec 2020 06:03:20
User entered '21 Dec 2020 00:03:15'	System	21 Dec 2020 06:03:20

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Dec 2020 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-28T23:13:48', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8586ba94-7861-44c2-a01c-532b7b97b509'	System	29 Dec 2020 05:13:57
User entered 'No (N)'	System	29 Dec 2020 05:13:57

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-28T23:13:49', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8586ba94-7861-44c2-a01c-532b7b97b509'	System	29 Dec 2020 05:13:57
User entered 'No (N)'	System	29 Dec 2020 05:13:57

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2020-12-28T23:13:52', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '8586ba94-7861-44c2-a01c-532b7b97b509'	System	29 Dec 2020 05:13:57
User entered '28 Dec 2020 23:13:52'	System	29 Dec 2020 05:13:57

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Dec 2020 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-04T00:04:31', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '1fa3c8d7-301a-4b43-911d-9e85a4f865eb'	System	04 Jan 2021 06:04:42
User entered 'No (N)'	System	04 Jan 2021 06:04:42

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-04T00:04:33', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '1fa3c8d7-301a-4b43-911d-9e85a4f865eb'	System	04 Jan 2021 06:04:42
User entered 'No (N)'	System	04 Jan 2021 06:04:42

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-04T00:04:37', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '1fa3c8d7-301a-4b43-911d-9e85a4f865eb'	System	04 Jan 2021 06:04:42
User entered '04 Jan 2021 00:04:37'	System	04 Jan 2021 06:04:42

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-11T23:37:42', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'add3947b-81c6-40ac-bfcc-cde2f85cd86b'	System	12 Jan 2021 05:37:53
User entered 'No (N)'	System	12 Jan 2021 05:37:53

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-11T23:37:45', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'add3947b-81c6-40ac-bfcc-cde2f85cd86b'	System	12 Jan 2021 05:37:53
User entered 'No (N)'	System	12 Jan 2021 05:37:53

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-11T23:37:48', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'add3947b-81c6-40ac-bfcc-cde2f85cd86b'	System	12 Jan 2021 05:37:53
User entered '11 Jan 2021 23:37:48'	System	12 Jan 2021 05:37:53

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-18T00:03:47', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'e9a4d024-7273-40bd-9624-cdad893fc44d'	System	25 Jan 2021 22:33:08
User entered 'No (N)'	System	25 Jan 2021 22:33:08

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-18T00:03:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'e9a4d024-7273-40bd-9624-cdad893fc44d'	System	25 Jan 2021 22:33:08
User entered 'No (N)'	System	25 Jan 2021 22:33:08

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-18T00:03:56', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'e9a4d024-7273-40bd-9624-cdad893fc44d'	System	25 Jan 2021 22:33:08
User entered '18 Jan 2021 00:03:56'	System	25 Jan 2021 22:33:08

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-25T16:32:57', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '6845e1da-3a62-4397-a342-8c5df0063ce2'	System	03 Feb 2021 01:58:36
User entered 'No (N)'	System	03 Feb 2021 01:58:36

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-25T16:32:59', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '6845e1da-3a62-4397-a342-8c5df0063ce2'	System	03 Feb 2021 01:58:36
User entered 'No (N)'	System	03 Feb 2021 01:58:36

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-01-25T16:33:03', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '6845e1da-3a62-4397-a342-8c5df0063ce2'	System	03 Feb 2021 01:58:36
User entered '25 Jan 2021 16:33:03'	System	03 Feb 2021 01:58:36

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Jan 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Jan 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-02T19:58:30', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '42adeebd-6687-4078-865e-f3d2888fa4f1'	System	03 Feb 2021 01:58:38
User entered 'No (N)'	System	03 Feb 2021 01:58:38

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-02T19:58:31', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '42adeebd-6687-4078-865e-f3d2888fa4f1'	System	03 Feb 2021 01:58:38
User entered 'No (N)'	System	03 Feb 2021 01:58:38

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-02T19:58:34', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '42adeebd-6687-4078-865e-f3d2888fa4f1'	System	03 Feb 2021 01:58:38
User entered '02 Feb 2021 19:58:34'	System	03 Feb 2021 01:58:38

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-08T21:28:50', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'b07aedfb-e4b2-4b72-8dcf-bf411d3653d8'	System	09 Feb 2021 03:28:59
User entered 'No (N)'	System	09 Feb 2021 03:28:59

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-08T21:28:53', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'b07aedfb-e4b2-4b72-8dcf-bf411d3653d8'	System	09 Feb 2021 03:28:59
User entered 'No (N)'	System	09 Feb 2021 03:28:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-08T21:28:56', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'b07aedfb-e4b2-4b72-8dcf-bf411d3653d8'	System	09 Feb 2021 03:28:59
User entered '08 Feb 2021 21:28:56'	System	09 Feb 2021 03:28:59

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-15T19:22:25', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f62c5d0-f5ce-4031-8e67-fcc9c4efd364'	System	16 Feb 2021 01:22:33
User entered 'No (N)'	System	16 Feb 2021 01:22:33

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-15T19:22:27', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f62c5d0-f5ce-4031-8e67-fcc9c4efd364'	System	16 Feb 2021 01:22:33
User entered 'No (N)'	System	16 Feb 2021 01:22:33

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-15T19:22:29', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9f62c5d0-f5ce-4031-8e67-fcc9c4efd364'	System	16 Feb 2021 01:22:33
User entered '15 Feb 2021 19:22:29'	System	16 Feb 2021 01:22:33

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-22T00:02:16', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'b90562fc-f356-47c9-b10a-95541421fbc2'	System	22 Feb 2021 06:02:30
User entered 'No (N)'	System	22 Feb 2021 06:02:30

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-22T00:02:22', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'b90562fc-f356-47c9-b10a-95541421fbc2'	System	22 Feb 2021 06:02:30
User entered 'No (N)'	System	22 Feb 2021 06:02:30

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-22T00:02:24', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'b90562fc-f356-47c9-b10a-95541421fbc2'	System	22 Feb 2021 06:02:30
User entered '22 Feb 2021 00:02:24'	System	22 Feb 2021 06:02:30

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Feb 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Feb 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-01T00:04:24-06:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4ac06837-d758-4e47-88c6-ab9dce1e3b33'	System	01 Mar 2021 06:04:34
User entered 'No (N)'	System	01 Mar 2021 06:04:34

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-01T00:04:26-06:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4ac06837-d758-4e47-88c6-ab9dce1e3b33'	System	01 Mar 2021 06:04:34
User entered 'No (N)'	System	01 Mar 2021 06:04:34

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-01T00:04:28-06:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '4ac06837-d758-4e47-88c6-ab9dce1e3b33'	System	01 Mar 2021 06:04:34
User entered '01 Mar 2021 00:04:28'	System	01 Mar 2021 06:04:34

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-08T07:42:59-06:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '465d811d-7833-484b-9521-a94e75f6e137'	System	08 Mar 2021 13:43:10
User entered 'No (N)'	System	08 Mar 2021 13:43:10

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-08T07:43:00-06:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '465d811d-7833-484b-9521-a94e75f6e137'	System	08 Mar 2021 13:43:10
User entered 'No (N)'	System	08 Mar 2021 13:43:10

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-08T07:43:03-06:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '465d811d-7833-484b-9521-a94e75f6e137'	System	08 Mar 2021 13:43:10
User entered '08 Mar 2021 07:43:03'	System	08 Mar 2021 13:43:10

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-15T21:07:50-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '97001841-d251-4125-ac5b-dcc7ed0b1d4e'	System	16 Mar 2021 02:09:07
User entered 'No (N)'	System	16 Mar 2021 02:09:07

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-15T21:07:52-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '97001841-d251-4125-ac5b-dcc7ed0b1d4e'	System	16 Mar 2021 02:09:07
User entered 'No (N)'	System	16 Mar 2021 02:09:07

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-15T21:07:55-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '97001841-d251-4125-ac5b-dcc7ed0b1d4e'	System	16 Mar 2021 02:09:07
User entered '15 Mar 2021 21:07:55'	System	16 Mar 2021 02:09:07

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-24T12:13:08-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '1ecafa87-8293-4151-93d9-e20a641dbeba'	System	24 Mar 2021 17:13:20
User entered 'No (N)'	System	24 Mar 2021 17:13:20

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-24T12:13:09-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '1ecafa87-8293-4151-93d9-e20a641dbeba'	System	24 Mar 2021 17:13:20
User entered 'No (N)'	System	24 Mar 2021 17:13:20

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-24T12:13:12-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '1ecafa87-8293-4151-93d9-e20a641dbeba'	System	24 Mar 2021 17:13:20
User entered '24 Mar 2021 12:13:12'	System	24 Mar 2021 17:13:20

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Mar 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-31T17:26:03-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '246df34b-1379-475b-b94e-1191a65753db'	System	31 Mar 2021 22:26:13
User entered 'No (N)'	System	31 Mar 2021 22:26:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-31T17:26:06-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '246df34b-1379-475b-b94e-1191a65753db'	System	31 Mar 2021 22:26:13
User entered 'No (N)'	System	31 Mar 2021 22:26:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-03-31T17:26:09-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '246df34b-1379-475b-b94e-1191a65753db'	System	31 Mar 2021 22:26:13
User entered '31 Mar 2021 17:26:09'	System	31 Mar 2021 22:26:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Mar 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-05T00:02:55-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'c971c75b-b2a8-436a-86e2-af9b8d42c258'	System	05 Apr 2021 05:03:07
User entered 'No (N)'	System	05 Apr 2021 05:03:07

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-05T00:02:57-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'c971c75b-b2a8-436a-86e2-af9b8d42c258'	System	05 Apr 2021 05:03:07
User entered 'No (N)'	System	05 Apr 2021 05:03:07

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-05T00:02:59-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'c971c75b-b2a8-436a-86e2-af9b8d42c258'	System	05 Apr 2021 05:03:07
User entered '05 Apr 2021 00:02:59'	System	05 Apr 2021 05:03:07

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-12T07:24:37-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'ec1cd0dc-de1d-4a7d-a071-5da3ce3207fa'	System	12 Apr 2021 12:24:47
User entered 'No (N)'	System	12 Apr 2021 12:24:47

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-12T07:24:39-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'ec1cd0dc-de1d-4a7d-a071-5da3ce3207fa'	System	12 Apr 2021 12:24:47
User entered 'No (N)'	System	12 Apr 2021 12:24:47

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-12T07:24:42-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: 'ec1cd0dc-de1d-4a7d-a071-5da3ce3207fa'	System	12 Apr 2021 12:24:47
User entered '12 Apr 2021 07:24:42'	System	12 Apr 2021 12:24:47

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-19T06:59:28-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9e2d2f97-4a49-4061-8c82-098106d10686'	System	19 Apr 2021 11:59:41
User entered 'No (N)'	System	19 Apr 2021 11:59:41

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-19T06:59:29-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9e2d2f97-4a49-4061-8c82-098106d10686'	System	19 Apr 2021 11:59:41
User entered 'No (N)'	System	19 Apr 2021 11:59:41

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-19T06:59:33-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '9e2d2f97-4a49-4061-8c82-098106d10686'	System	19 Apr 2021 11:59:41
User entered '19 Apr 2021 06:59:33'	System	19 Apr 2021 11:59:41

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 05:47:13

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-28T07:15:50-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '3d9c1893-c31a-4a0d-9b28-b9c7d3ece609'	System	28 Apr 2021 23:25:41
User entered 'No (N)'	System	28 Apr 2021 23:25:41

US3492078

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 07:56:52

Have you been exposed to someone with 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 (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-28T07:15:52-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '3d9c1893-c31a-4a0d-9b28-b9c7d3ece609'	System	28 Apr 2021 23:25:41
User entered 'No (N)'	System	28 Apr 2021 23:25:41

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Date and time of submission

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-04-28T07:15:54-05:00', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '3d9c1893-c31a-4a0d-9b28-b9c7d3ece609'	System	28 Apr 2021 23:25:41
User entered '28 Apr 2021 07:15:54'	System	28 Apr 2021 23:25:41

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Apr 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Apr 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 May 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 May 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Jun 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Jun 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Jul 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Jul 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Aug 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Aug 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Sep 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Sep 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Oct 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Oct 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Nov 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Nov 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Dec 2021 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 Dec 2021 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Jan 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 Jan 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Feb 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Feb 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Mar 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Mar 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Apr 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Apr 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 05:47:13

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Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 May 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 May 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '06 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '13 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '20 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Jun 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '27 Jun 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '18 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '25 Jul 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Jul 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '01 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '08 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '15 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '22 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Aug 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '29 Aug 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '02 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '05 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '09 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '12 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '16 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '19 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '23 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '26 Sep 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '30 Sep 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '03 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '10 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '14 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '17 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '21 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '24 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '28 Oct 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '31 Oct 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '04 Nov 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Open Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '07 Nov 2022 00:01'	System	20 Nov 2020 05:47:13

US3492078
Folder: New Safety Follow Up Diary (1)
Form: Safety Follow Up Diary
Generated On: 10 Jun 2021 07:56:52
Patient Cloud Close Date & Time

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 05:47:13
Amendment Manager: User entered '11 Nov 2022 23:59'	System	20 Nov 2020 05:47:13

US3492078

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 07:56:52

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-28T19:30:26', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '6991e5d0-da8b-4281-ad07-e35b826cdddf'	System	01 Mar 2021 01:30:35
User entered 'No (N)'	System	01 Mar 2021 01:30:35

US3492078
Folder: Cosmetic Injections and Dermal Fillers
Form: Cosmetic Injection_ Dermal Filler eDiary (1)
Generated On: 10 Jun 2021 07:56:52
Date & Time of Submission

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:52:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (03EA9B38-6A61-40CE-9EE9-9575E8D451AF)', Time: '2021-02-28T19:30:29', User OID: 'PatientReportedOutcome (US3492078)', ODM File OID: '6991e5d0-da8b-4281-ad07-e35b826cdddf'	System	01 Mar 2021 01:30:35
User entered '28 Feb 2021 19:30:29'	System	01 Mar 2021 01:30:35

US3492078
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:13:19

US3492078
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '24 Nov 2020'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:13:19

FDA-CBER-2022-1614-2447971

US3492078
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:13:19

FDA-CBER-2022-1614-2447972

US3492078
Folder: Safety Call Day 85 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:13:19

FDA-CBER-2022-1614-2447973

US3492078
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	25 Nov 2020 16:14:11

US3492078
Folder: Safety Call Day 85 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:47:10
User entered '1'	System	25 Nov 2020 16:14:11

FDA-CBER-2022-1614-2447975

US3492078
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 15:42:03

US3492078
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '30 Dec 2020'	(b) (4), (b) (6)	30 Dec 2020 15:42:03

FDA-CBER-2022-1614-2447977

US3492078
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	30 Dec 2020 15:42:03

US3492078
Folder: Safety Call Day 119 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	(b) (4), (b) (6)	30 Dec 2020 15:42:03

FDA-CBER-2022-1614-2447979

US3492078
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	30 Dec 2020 15:42:13

US3492078
Folder: Safety Call Day 119 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User entered '1'	System	30 Dec 2020 15:42:13

FDA-CBER-2022-1614-2447981

US3492078
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:31:15

FDA-CBER-2022-1614-2447982

US3492078
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '28 Jan 2021'	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:31:15

US3492078
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Contact Made (CONTACT MADE)'	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:31:15

FDA-CBER-2022-1614-2447984

US3492078
Folder: Safety Call Day 149 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:31:15

FDA-CBER-2022-1614-2447985

US3492078
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Ian Feather (b) (4) (b) (4)	28 Jan 2021 17:31:22

US3492078
Folder: Safety Call Day 149 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User entered '1'	System	28 Jan 2021 17:31:22

US3492078
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	26 Feb 2021 21:21:41

US3492078
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered '26 Feb 2021'	Nia Moragne-O'Neal (b) (4)	26 Feb 2021 21:21:41

US3492078
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	26 Feb 2021 21:21:41

US3492078
Folder: Safety Call Day 179 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered empty.	Nia Moragne-O'Neal (b) (4)	26 Feb 2021 21:21:41

US3492078
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	26 Feb 2021 21:21:44

US3492078
Folder: Safety Call Day 179 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 09:25:58
User entered '1'	System	26 Feb 2021 21:21:44

FDA-CBER-2022-1614-2447993

US3492078
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was this visit performed?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:02:37

FDA-CBER-2022-1614-2447994

US3492078
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '31 Mar 2021'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:02:37

FDA-CBER-2022-1614-2447995

US3492078
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Clinic (Clinic)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:02:37

FDA-CBER-2022-1614-2447996

US3492078
Folder: Visit 4 Day 209 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Folder OID

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 19:02:37

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Were vital signs assessed?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2447998

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Date of assessment *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '31 Mar 2021'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Time of assessment *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '13:46'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448000

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Vital Signs Date and Time (derived)

Audit	User	Time (GMT)
User entered '31 Mar 2021 13:46'	System	31 Mar 2021 19:03:25

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Temperature *(xxx.x)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '36.3' C	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448002

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Route of measurement

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Other (Other)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
If Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'tympanic'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448004

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Pulse *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '81'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448005

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Pulse units

Audit	User	Time (GMT)
User entered 'bpm'	System	31 Mar 2021 19:03:25

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '16'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448007

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Respiratory Rate units

Audit	User	Time (GMT)
User entered 'breaths/min'	System	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448008

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '125'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448009

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Systolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 19:03:25

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure *(xxx)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '84'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448011

US3492078
Folder: Visit 4 Day 209 (1)
Form: Vital Signs
Generated On: 10 Jun 2021 07:56:52
Diastolic Blood Pressure units

Audit	User	Time (GMT)
User entered 'mmHg'	System	31 Mar 2021 19:03:25

FDA-CBER-2022-1614-2448012

US3492078
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:34

FDA-CBER-2022-1614-2448013

US3492078
Folder: Visit 4 Day 209 (1)
Form: Physical Examination
Generated On: 10 Jun 2021 07:56:52
Date of examination *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '31 Mar 2021'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:34

FDA-CBER-2022-1614-2448014

US3492078
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	31 Mar 2021 19:26:17

FDA-CBER-2022-1614-2448015

US3492078
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '31 Mar 2021'	Gizelle Alvarez (b) (4) (b) (4)	31 Mar 2021 19:26:17

US3492078
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '14:10'	Gizelle Alvarez (b) (4) (b) (4)	31 Mar 2021 19:26:17

FDA-CBER-2022-1614-2448017

US3492078
Folder: Visit 4 Day 209 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
User entered '31 Mar 2021 14:10'	System	31 Mar 2021 19:26:17

US3492078
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:03:38

FDA-CBER-2022-1614-2448019

US3492078
Folder: Visit 4 Day 209 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 19:03:38

US3492078
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Was Contact Attempted?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	29 Apr 2021 19:05:37

FDA-CBER-2022-1614-2448021

US3492078
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Date of Contact or Contact Attempt *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '29 Apr 2021'	Nia Moragne-O'Neal (b) (4)	29 Apr 2021 19:05:37

US3492078
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Please select one status for the follow-up contact

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Contact Made (CONTACT MADE)'	Nia Moragne-O'Neal (b) (4)	29 Apr 2021 19:05:37

FDA-CBER-2022-1614-2448023

US3492078
Folder: Safety Call Day 239 (1)
Form: Safety Call
Generated On: 10 Jun 2021 07:56:52
Comments

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Nia Moragne-O'Neal (b) (4)	29 Apr 2021 19:05:37

FDA-CBER-2022-1614-2448024

US3492078
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Is the participant continuing to the next visit?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Yes (Y)'	Nia Moragne-O'Neal (b) (4)	29 Apr 2021 19:05:40

FDA-CBER-2022-1614-2448025

US3492078
Folder: Safety Call Day 239 (1)
Form: Continuing
Generated On: 10 Jun 2021 07:56:52
Continuing Flag

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 19:05:40

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was this visit performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:37

FDA-CBER-2022-1614-2448027

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15 Jan 2021'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:37

FDA-CBER-2022-1614-2448028

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Clinic (Clinic)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:37

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Visit Date
Generated On: 10 Jun 2021 07:56:52
Folder OID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 21:29:37

FDA-CBER-2022-1614-2448030

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Date of updated informed consent *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15 Jan 2021' reason for change: Data Entry Error	Lorna Sanchez McCann (b) (4)	21 Jan 2021 19:56:05
User entered '24 Dec 2020'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

FDA-CBER-2022-1614-2448031

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:44:25

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Was the participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Under what version of the Protocol was the Participant unblinded?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:44:25

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Date of unblinding *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15 Jan 2021'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Participant randomization assignment

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mRNA-1273 (mRNA-1273)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Actual Dose 1

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 14:15:59
User entered 'mRNA-1273 (mRNA-1273)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Actual Dose 2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 14:15:59
User entered 'mRNA-1273 (mRNA-1273)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Will participant receive mRNA-1273?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:29:55

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Placebo Only Flag

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User entered empty.	System	15 Jan 2021 21:29:55

FDA-CBER-2022-1614-2448040

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Unblinding
Generated On: 10 Jun 2021 07:56:52
Continuing with mRNA-1273

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User entered empty.	System	15 Jan 2021 21:29:55

FDA-CBER-2022-1614-2448041

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:34:43

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15 Jan 2021'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:34:43

FDA-CBER-2022-1614-2448043

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15:15'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:34:43

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Immunogenicity Assessment
Generated On: 10 Jun 2021 07:56:52
Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User entered '15 Jan 2021 15:15'	System	15 Jan 2021 21:34:43

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 07:56:52
Was the sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:34:53

FDA-CBER-2022-1614-2448046

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 07:56:52
Collection date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15 Jan 2021'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:34:53

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 07:56:52
Collection time *(00:00 - 23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '15:30'	Gizelle Alvarez (b) (4) (b) (4)	15 Jan 2021 21:34:53

US3492078
Folder: Participant Decision Visit / OL-D1 (1)
Form: Central Laboratory - Nasopharyngeal Swab (Single)
Generated On: 10 Jun 2021 07:56:52
Collection Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:03:05
User entered '15 Jan 2021 15:30'	System	15 Jan 2021 21:34:53

US3492078
Folder: Adverse Events
Form: Adverse Events Summary
Generated On: 10 Jun 2021 07:56:52
Did the participant experience any adverse events?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:35
User entered 'Yes (Y)'	Michelle Agnoli (b) (4) (b) (4)	09 Oct 2020 21:22:54

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17

FDA-CBER-2022-1614-2448051

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:30:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 18:30:43
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Injection site pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:42:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 19:42:34
Data point term sent to Coder	System	19 Oct 2020 19:41:15
User entered 'Soreness at injection site'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

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US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:41
User closed query 'Per DM CLR - RQ: Site's response noted. Since this is verbally reported, Note that any Solicited Adverse Reaction that are NOT captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 16:27:01
Query 'Per DM CLR - RQ: Site's response noted. Since this is verbally reported, Note that any Solicited Adverse Reaction that are NOT captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate. ' answered with '----------thank you. corrected----------' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:27:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 19:27:31
User opened query 'Per DM CLR - RQ: Site's response noted. Since this is verbally reported, Note that any Solicited Adverse Reaction that are NOT captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 02:35:14
User closed query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 15:36:09

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' answered with 'patient verbally notified site of soreness at injection site' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:18:23
User opened query 'Per DM CLR: Was this a Solicited Adverse Reaction? = YES. However, there is no corresponding eDiary data recorded for this symptom on the given date. Please confirm if this is verbally reported and note that any Solicited Adverse Reaction that are not captured in eDiary are to be recorded as Unsolicited Adverse Event. Please review and update as appropriate, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 01:26:51
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '5 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '17:00'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User entered '5 Sep 2020 17:00'	System	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '7 Sep 2020'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User closed query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 19:42:44
User entered '12:00' reason for change: Per Query Resolution	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:42:44
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Oct 2020 19:40:50
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User entered '7 Sep 2020 12:00'	System	19 Oct 2020 19:42:44
User entered empty.	System	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

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US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Related (RELATED)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Related (RELATED)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'None (NONE)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'SOLICITED AE BUT COULD NOT GET EPRO TO WORK DESPITE CALLS TO MEDIDATA HELPDESK-Correction-NOT SOLICITED since not captured on diary and reported verbally to site' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	13 Nov 2020 21:19:19
User entered 'solicited AE but could not get ePRO to work despite calls to Medidata helpdesk'	Andrea Wendrow (b) (4) (b) (4)	19 Oct 2020 19:40:50

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US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User entered '0'	System	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17
User entered '0'	System	19 Oct 2020 19:40:50

US3492078
Folder: Adverse Events
Form: Adverse Events (2)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:17

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US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
AEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 14:23:47
User entered 'USA-US101-2020-mRNA-1273-P301000006'	System	23 Nov 2020 14:23:42
User entered 'New'	(b) (4), (b) (6)	23 Nov 2020 14:23:42

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US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User coded data point as SOC: Vascular disorders, HLGT: Vascular haemorrhagic disorders, HLT: Haemorrhages NEC, PT: Haematoma, LLT: Hematoma - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:26:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Nov 2020 12:26:00
Data point term sent to Coder	System	20 Nov 2020 23:35:39
Coding entries removed.	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'Hematoma of the R leg' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Pain in extremity, LLT: Unilateral leg pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:06:30
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Nov 2020 07:06:30
Data point term sent to Coder	System	06 Nov 2020 21:57:07
User entered 'right upper leg pain'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

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US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

FDA-CBER-2022-1614-2448091

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '03 Nov 2020'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

FDA-CBER-2022-1614-2448094

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 22:42:49
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User closed query 'PV Query: Please clarify event end date. Although the patient was hospitalized for the event until 17Nov2020, the stop date is reported as 13Nov2020.' (Site from Safety).	(b) (4), (b) (6)	08 Mar 2021 16:40:25
Query 'PV Query: Please clarify event end date. Although the patient was hospitalized for the event until 17Nov2020, the stop date is reported as 13Nov2020.' answered with 'the embolization was on 12Nov2020 which resolved the condition' (Site from Safety).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 19:54:34
User opened query 'PV Query: Please clarify event end date. Although the patient was hospitalized for the event until 17Nov2020, the stop date is reported as 13Nov2020.' (Site from Safety).	(b) (4), (b) (6)	02 Mar 2021 14:08:01
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:39:18
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 18:39:15
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User closed query 'PV Query: Please clarify the event resolution date. The event has been reported as resolved on 11 Nov 2020 but the subject was admitted that day for the event.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:07:34
Query 'PV Query: Please clarify the event resolution date. The event has been reported as resolved on 11 Nov 2020 but the subject was admitted that day for the event.' answered with 'updated info' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:17:22
User entered '13 Nov 2020' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:17:05
User opened query 'PV Query: Please clarify the event resolution date. The event has been reported as resolved on 11 Nov 2020 but the subject was admitted that day for the event.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:48:37
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 22:46:22

FDA-CBER-2022-1614-2448097

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	20 Nov 2020 22:46:22
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Nov 2020 22:42:49
User entered '11 Nov 2020' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 22:42:49
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

FDA-CBER-2022-1614-2448098

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Severity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Yes (Y)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'No (N)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4)	20 Nov 2020 23:34:45
User entered '0'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:20
User entered '10 Nov 2020' reason for change: New Information	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:39:57
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:31
Signature has been broken.	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:31
User entered '11 Nov 2020' reason for change: New Information	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:31
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '10 Nov 2020' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:15:16
User entered '11 Nov 2020' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '17 Nov 2020' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'None (NONE)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered '1'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Concomitant Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:20
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 13:11:38
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'no con meds, but con meds discontinued as per narrative' (Site from DM).	Diana Bahena (b) (4) (b) (4)	03 Feb 2021 18:42:10
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	03 Feb 2021 18:41:42
User entered '0' reason for change: New Information	Diana Bahena (b) (4) (b) (4)	03 Feb 2021 18:41:42
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:52:33
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '1' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered '0'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 22:46:22
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty; reason for change Data Entry Error	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45
User entered 'hematoma of the right leg' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 22:46:22
User entered empty.	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User closed query 'PV Query: Please clarify that date of embolization was 13 Nov 2021 and Eliquis was resumed on 16 Nov 2020 (vs. September 2020 as reported in answered queries on 07Apr2021)' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:19:28
Query 'PV Query: Please clarify that date of embolization was 13 Nov 2021 and Eliquis was resumed on 16 Nov 2020 (vs. September 2020 as reported in answered queries on 07Apr2021)' answered with 'Confirming embolization performed 13NOV2020 and Eliquis resumed 16NOV2020' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	12 Apr 2021 22:38:22
User opened query 'PV Query: Please clarify that date of embolization was 13 Nov 2021 and Eliquis was resumed on 16 Nov 2020 (vs. September 2020 as reported in answered queries on 07Apr2021)' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 22:18:48
User closed query 'PV query: As the event resolved on 13 Sep 2020, however the subject was not discharged until 17 Sep 2020 -Please confirm if the subject experienced any additional SAEs that prolonged the subject's hospitalization?' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:25:21
User closed query 'PV query: Please clarify date of embolization, per query response this was completed 12 Sep 2020, however per narrative it was done on 13 Sep 2020. If needed, please update SAE narrative with correct date. ' (Site from Safety).	(b) (4), (b) (6)	08 Apr 2021 13:25:11
Query 'PV query: As the event resolved on 13 Sep 2020, however the subject was not discharged until 17 Sep 2020 -Please confirm if the subject experienced any additional SAEs that prolonged the subject's hospitalization?' answered with 'No additional SAE's, patient remained hospitalized to resume anticoagulant (Eliquis) on 16SEP2020 after embolization' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 19:03:47

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
Query 'PV query: Please clarify date of embolization, per query response this was completed 12 Sep 2020, however per narrative it was done on 13 Sep 2020. If needed, please update SAE narrative with correct date. ' answered with 'Embolization performed 13SEP2020' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 18:57:38
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:20
User opened query 'PV query: As the event resolved on 13 Sep 2020, however the subject was not discharged until 17 Sep 2020 -Please confirm if the subject experienced any additional SAEs that prolonged the subject's hospitalization?' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:16:39
User opened query 'PV query: Please clarify date of embolization, per query response this was completed 12 Sep 2020, however per narrative it was done on 13 Sep 2020. If needed, please update SAE narrative with correct date. ' (Site from Safety).	(b) (4), (b) (6)	11 Mar 2021 21:16:29
User closed query ' PER CDM RQ: Response noted that patient received 3 UNITS PRBC's. Any procedures performed after patient is enrolled in study should be recorded on Concomitant Procedure form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:24:56
Query ' PER CDM RQ: Response noted that patient received 3 UNITS PRBC's. Any procedures performed after patient is enrolled in study should be recorded on Concomitant Procedure form. Kindly review and update else clarify.' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:34:38
User opened query ' PER CDM RQ: Response noted that patient received 3 UNITS PRBC's. Any procedures performed after patient is enrolled in study should be recorded on Concomitant Procedure form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:44:53
Query 'PER CDM RQ: Any procedures performed after patient is enrolled in study should be recorded on Concomitant Procedure form. Kindly review and update else clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:44:16

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Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User opened query 'PER CDM RQ: Any procedures performed after patient is enrolled in study should be recorded on Concomitant Procedure form. Kindly review and update else clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:44:06
User closed query 'Per DM CLR: SAE Narrative = OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 13:44:06
User closed query 'Per DM CLR: Narrative = SUBJECT HOSPITALIZED 11NOV2020. However, this does not correspond to the date of admission. Please review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:06:29
User closed query 'Per DM CLR: Narrative = WORK UP INCLUDED RLE CT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 16:30:02
Query 'Per DM CLR: Narrative = WORK UP INCLUDED RLE CT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:40:03

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS WORKING OUT ON TOTAL GYM MACHINE AND INJURED RIGHT UPPER LEG MUSCLE. ROM AND STRENGTH WITHIN NORMAL LIMITS AND BASELINE FOR PARTICIPANT. SUBJECT HOSPITALIZED 10NOV 2020 THROUGH 17NOV2020 FOR PAIN AND SWELLING IN R LEG. RLE CT WHICH SHOWED LARGE INTRAMUSCULAR HEMATOMA OF THE VASTUS LATERALUS WITH MULTIPLE FOCI OF ACTIVE EXTRAVASATION FROM BRANCHES OF THE PROFUNDA FEMORAL ARTERY. NO DVT. APIXABAN HELD AND ASA DISCONTINUED. COLONOSCOPY PERFORMED FOR SIGNS OF BLEEDING AND COMPLAINT OF INTERMITTENT DIARRHEA THAT HE DID NOT REPORT AT D57 NOR ON EDIARY OR SAFETY CALLS. OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. VASCULAR ANGIOGRAM AND EMBOLIZATION PERFORMED ON13NOV2020. AT DISCHARGE APIXABAN RESTARTED AT 2.5MG BID' reason for change: New Information	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:39:57
Query 'Per DM CLR: Narrative = SUBJECT HOSPITALIZED 11NOV2020. However, this does not correspond to the date of admission. Please review and reconcile as appropriate. ' answered with 'PPt went to ER on late 10 Nov2020, actually admitted on 11Nov2020' (Site from DM).	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:54
DataPoint Un-verified.	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:31
Signature has been broken.	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:31

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS WORKING OUT ON TOTAL GYM MACHINE AND INJURED RIGHT UPPER LEG MUSCLE. ROM AND STRENGTH WITHIN NORMAL LIMITS AND BASELINE FOR PARTICIPANT. SUBJECT HOSPITALIZED 11NOV 2020 THROUGH 17NOV2020 FOR PAIN AND SWELLING IN R LEG. RLE CT WHICH SHOWED LARGE INTRAMUSCULAR HEMATOMA OF THE VASTUS LATERALUS WITH MULTIPLE FOCI OF ACTIVE EXTRAVASATION FROM BRANCHES OF THE PROFUNDA FEMORAL ARTERY. NO DVT. APIXABAN HELD AND ASA DISCONTINUED. COLONOSCOPY PERFORMED FOR SIGNS OF BLEEDING AND COMPLAINT OF INTERMITTENT DIARRHEA THAT HE DID NOT REPORT AT D57 NOR ON EDIARY OR SAFETY CALLS. OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. VASCULAR ANGIOGRAM AND EMBOLIZATION PERFORMED ON13NOV2020. AT DISCHARGE APIXABAN RESTARTED AT 2.5MG BID' reason for change: New Information	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:37:31
User opened query 'Per DM CLR: Narrative = WORK UP INCLUDED RLE CT. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:11:31
User opened query 'Per DM CLR: Narrative = SUBJECT HOSPITALIZED 11NOV2020. However, this does not correspond to the date of admission. Please review and reconcile as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 03:11:14
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41

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US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'Which is the appropriate eCRF in which to document the 3 units PRBC's?' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	21 Jan 2021 20:34:07
User opened query 'Per DM CLR: SAE Narrative = OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. However, these information were not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Jan 2021 05:13:47
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 Nov 2020 21:07:31
User closed query 'PV Query: Please provide the results of vascular angiogram and colonoscopy. If not available, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:07:29
User closed query 'PV Query: Did the subject receive any other treatment other than PRBCs? If yes, please include them to concomitant medication eCRF. If no, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:07:27
User closed query 'PV Query: It was reported that the subject had a colonoscopy performed for concerns of bleeding and intermittent diarrhea. Please report if these indications and/or the findings from the colonoscopy meet AE/SAE reporting criteria. If yes, please report accordingly. If no, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 21:07:26
Query 'PV Query: It was reported that the subject had a colonoscopy performed for concerns of bleeding and intermittent diarrhea. Please report if these indications and/or the findings from the colonoscopy meet AE/SAE reporting criteria. If yes, please report accordingly. If no, please state so.' answered with 'Colonoscopy findings do not meet AE/SAE reporting criteria' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:42:01

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US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
Query 'PV Query: Did the subject receive any other treatment other than PRBCs? If yes, please include them to concomitant medication eCRF. If no, please state so.' answered with 'Con meds from hospitalization updated' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:40:31
Query 'PV Query: Please provide the results of vascular angiogram and colonoscopy. If not available, please state so.' answered with 'Vascular angiogram confirmed results of RLE CT as noted in narrative and embolization performed on effected vessel. Colonoscopy was negative for signs of bleeding or active signs of colitis.' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:40:13
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 'NP swab for Rapid SARS-CoV-2 by PCR collected on 10NOV2020 and reported as not detected' (Site from Safety).	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:37:32
User opened query 'PV Query: It was reported that the subject had a colonoscopy performed for concerns of bleeding and intermittent diarrhea. Please report if these indications and/or the findings from the colonoscopy meet AE/SAE reporting criteria. If yes, please report accordingly. If no, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:49:15
User opened query 'PV Query: Did the subject receive any other treatment other than PRBCs? If yes, please include them to concomitant medication eCRF. If no, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:48:55
User opened query 'PV Query: Please provide the results of vascular angiogram and colonoscopy. If not available, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:48:11
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)	30 Nov 2020 15:47:55

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User entered 'PARTICIPANT WAS WORKING OUT ON TOTAL GYM MACHINE AND INJURED RIGHT UPPER LEG MUSCLE. ROM AND STRENGTH WITHIN NORMAL LIMITS AND BASELINE FOR PARTICIPANT. SUBJECT HOSPITALIZED 11NOV 2020 THROUGH 17NOV2020 FOR PAIN AND SWELLING IN R LEG. WORK UP INCLUDED RLE CT WHICH SHOWED LARGE INTRAMUSCULAR HEMATOMA OF THE VASTUS LATERALUS WITH MULTIPLE FOCI OF ACTIVE EXTRAVASATION FROM BRANCHES OF THE PROFUNDA FEMORAL ARTERY. NO DVT. APIXABAN HELD AND ASA DISCONTINUED. COLONOSCOPY PERFORMED FOR SIGNS OF BLEEDING AND COMPLAINT OF INTERMITTENT DIARRHEA THAT HE DID NOT REPORT AT D57 NOR ON EDIARY OR SAFETY CALLS. OVER COURSE OF ADMISSION RECEIVED 3 UNITS PRBCS. VASCULAR ANGIOGRAM AND EMBOLIZATION PERFORMED ON13NOV2020. AT DISCHARGE APIXABAN RESTARTED AT 2.5MG BID' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:20:27
User entered 'PARTICIPANT WAS WORKING OUT ON TOTAL GYM MACHINE AND INJURED RIGHT UPPER LEG MUSCLE. ROM AND STRENGTH WITHIN NORMAL LIMITS AND BASELINE FOR PARTICIPANT. Subject hospitalized 11Nov 2020 through 17Nov2020 for pain and swelling in R leg. Work up included RLE CT which showed large intramuscular hematoma of the vastus lateralus with multiple foci of active extravasation from branches of the profunda femoral artery. No DVT. Apixaban held and ASA discontinued. Colonoscopy performed for signs of bleeding and complaint of intermittent diarrhea that he did not report at D57 nor on ediary or safety calls. Over course of admission received 3 units PRBCs. Vascular angiogram and embolization performed on13Nov202., At discharge apixaban restarted at 2.5mg bid' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	20 Nov 2020 23:34:45

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User entered 'Participant was working out on total gym machine and injured right upper leg muscle. ROM and strength within normal limits and baseline for participant.'	(b) (4), (b) (6)	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 23:34:45
User entered '0'	System	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	20 Nov 2020 23:34:45
User entered '0'	System	06 Nov 2020 21:56:46

US3492078
Folder: Adverse Events
Form: Adverse Events (3)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	20 Nov 2020 23:34:45

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
AEID

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24

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US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Adverse event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:41
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) (6)	15 Jan 2021 21:23:03
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 '----------Participant did not report Diarrhea symptoms to clinic. Details for this event came from participant's medical records from his hospitalization which were faxed to us on 20 Nov 2020.---------- ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:46:27
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)	14 Dec 2020 18:42:52
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 21:38:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 21:38:31
Data point term sent to Coder	System	25 Nov 2020 21:37:28
User entered 'diarrhea'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Was this a medically-attended AE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '07 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
AE start date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User entered empty.	System	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '18 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
End time *(00:00-23:59)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

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US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
AE End Date and Time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User entered empty.	System	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Severity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Is the adverse event serious?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

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US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

FDA-CBER-2022-1614-2448149

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

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US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

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US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

FDA-CBER-2022-1614-2448156

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Relationship to investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Relationship to Study Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

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US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Concomitant Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Concomitant Procedure

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 11:22:02
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'Colonoscopy in con procedures' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	02 Feb 2021 16:48:47
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 04:52:49
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Outcome

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:41
User entered 'SUBJECT HAS REPORTED DIARRHEA, HOSPITAL RECORDS INDICATE 3 WEEKS, HOWEVER, CONFIRMATION WITH SON IS 3 DAYS PRIOR TO ADMISSION WHICH WOULD BE more CONSISTENT WITH NO COMMENTS IN e diaries or safety calls' reason for change: New Information	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:45:02
User entered 'subject has reported diarrhea, hospital records indicate 3 weeks, however, confirmation with son is 3 DAYS prior to admission which would be consistent with no comments in'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User entered '0'	System	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24
User entered '1'	System	25 Nov 2020 21:36:54

US3492078
Folder: Adverse Events
Form: Adverse Events (4)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 20:07:24

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US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
AEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 15:27:38
User entered 'USA-US101-2021-mRNA-1273-P301000012'	System	30 Apr 2021 15:27:26
User entered 'New'	(b) (4), (b) (6)	30 Apr 2021 15:27:26

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Adverse event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pleural disorders, HLT: Pneumothorax and pleural effusions NEC, PT: Pleural effusion, LLT: Pleural effusion - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 08:16:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	30 Apr 2021 08:16:24
Data point term sent to Coder	System	29 Apr 2021 22:47:25
User entered 'Right Lung Pleural Effusion'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Was this a medically-attended AE?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Was this a Solicited Adverse Reaction?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Is this event a confirmed diagnosis of Symptomatic Covid-19?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '24 Apr 2021'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

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US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Start time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
AE start date and time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, end date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

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US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
End time *(00:00-23:59)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
AE End Date and Time (derived)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Severity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Grade 4 (Grade 4)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Is the adverse event serious?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Yes (Y)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

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US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
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)	01 May 2021 10:53:37
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
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 'Still hospitalized, not in ICU' (Site from System).	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:47:39
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	29 Apr 2021 22:46:44
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Hospital Admission Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '24 Apr 2021'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Hospital Discharge Date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'No (N)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Relationship to investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Relationship to Study Procedure

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Not Related (NOT RELATED)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
None

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Concomitant Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '0'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

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US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Concomitant Procedure

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '1'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Outcome

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Narrative

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Subject's son reported during safety call on 29Apr2021 that subject was hospitalized for right pleural effusion on 24Apr2021, chest tube placed on same day. COVID PCR test negative on admisson. Currently under observation. Medical records requested.'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:46:44

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US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Serious Adverse Event Derived (CSA Programming Field Ony)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	29 Apr 2021 22:46:44

US3492078
Folder: Adverse Events
Form: Adverse Events (5)
Generated On: 10 Jun 2021 07:56:52
Admitted to ICU Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 22:46:44

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination Summary
Generated On: 10 Jun 2021 07:56:52
Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:20:01

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:22:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:22:44
Data point term sent to Coder	System	05 Sep 2020 20:22:08
User entered 'Aspirin'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

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US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Coronary artery disease'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '81'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2019'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:42:23
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '10 Nov 2020' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:42:23
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User entered '1'	System	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User entered '1'	System	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (1)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:53
User entered '804 (804)'	System	05 Sep 2020 20:21:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:53:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:53:46
Data point term sent to Coder	System	07 Apr 2021 18:52:49
Coding entries removed.	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 18:52:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Mar 2021 20:32:57
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 Mar 2021 20:32:57
Data point term sent to Coder	System	05 Mar 2021 20:32:25
Coding entries removed.	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:32:23
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:24:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:24:45
Data point term sent to Coder	System	05 Sep 2020 20:24:10

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
User entered 'Eliquis'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
Signature has been broken.	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 18:52:03
User entered 'S/P history of multiple cva's' reason for change: Per Query Resolution	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 18:52:03
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:21:17
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'updated' (Site from DM).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:32:29
Signature has been broken.	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:32:23
User entered 's/p CVA' reason for change: Data Entry Error	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:32:23
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 22:45:55
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Cerebrovascular disease'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '5'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 06:34:48
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'Taken for history of multiple CVA's' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	07 Apr 2021 18:52:11
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 08:10:22
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

FDA-CBER-2022-1614-2448235

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:43:01
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '10 Nov 2020' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:43:01
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User entered '1'	System	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User entered '1'	System	05 Sep 2020 20:23:34

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (2)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:56
User entered '804 (804)'	System	05 Sep 2020 20:23:34

FDA-CBER-2022-1614-2448242

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE, PRODUCTSYNONYM: LASIX [FUROSEMIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:25:46
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 Sep 2020 20:25:46
Data point term sent to Coder	System	05 Sep 2020 20:25:11
User entered 'Lasix'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Congestive heart failure'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '20'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

FDA-CBER-2022-1614-2448246

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

FDA-CBER-2022-1614-2448248

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2018'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (3)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:24:46

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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 Sep 2020 20:27:46
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 Sep 2020 20:27:46
Data point term sent to Coder	System	05 Sep 2020 20:26:12
User entered 'Atorvastatin'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User closed query 'Per DM Re-Query: The start date of HYPERLIPIDEMIA is 2003 which is prior to the condition reported in medical History form. Please reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 15:29:26
Query 'Per DM Re-Query: The start date of HYPERLIPIDEMIA is 2003 which is prior to the condition reported in medical History form. Please reconcile. Thank you!' answered with 'corrected' (Site from DM).	Marla Schwarber (b) (4) (b) (4)	09 Nov 2020 19:33:59
User opened query 'Per DM Re-Query: The start date of HYPERLIPIDEMIA is 2003 which is prior to the condition reported in medical History form. Please reconcile. Thank you!' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 04:24:32
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)	05 Nov 2020 04:24:32
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 'completed' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:27:39
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 09:20:45
User entered 'Hyperlipidemia'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '40'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2003'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (4)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:26:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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)	23 Oct 2020 21:30:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 21:30:42
Data point term sent to Coder	System	23 Oct 2020 21:29:32
Coding entries removed.	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:28:50
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)	06 Sep 2020 05:48:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 05:48:46
Data point term sent to Coder	System	05 Sep 2020 20:28:13
User entered 'Metoprolol'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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)	05 Nov 2020 04:27:22
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 'completed' (Site from DM).	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:28:59
User entered 'atrial fibrillation' reason for change: Per Query Resolution	Michelle Agnoli (b) (4) (b) (4)	23 Oct 2020 21:28:50
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)	23 Oct 2020 09:20:58
User entered 'Heart rate control'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '25'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

FDA-CBER-2022-1614-2448287

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2016'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:43:50
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '17 Nov 2020' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:43:50
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:27:17

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User entered '1'	System	05 Sep 2020 20:27:17

FDA-CBER-2022-1614-2448294

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User entered '1'	System	05 Sep 2020 20:27:17

FDA-CBER-2022-1614-2448295

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (5)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:47
User entered '804 (804)'	System	05 Sep 2020 20:27:17

FDA-CBER-2022-1614-2448296

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: SELECTIVE SEROTONIN REUPTAKE INHIBITORS, PRODUCT: SERTRALINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 20:29:46
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 Sep 2020 20:29:46
Data point term sent to Coder	System	05 Sep 2020 20:29:13
User entered 'Sertraline'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Depression'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '25'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

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US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'UN UNK 2017'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (6)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	05 Sep 2020 20:28:25

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 20:47:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 20:47:21
Data point term sent to Coder	System	25 Nov 2020 20:46:40
User entered 'eliquis'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Thank you for the response. Please confirm the recorded indication is correct else update the indication to "HEMATOMA OF THE R LEG" if appropriate per response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 22:37:50
Query 'Per CDM re-query: Thank you for the response. Please confirm the recorded indication is correct else update the indication to "HEMATOMA OF THE R LEG" if appropriate per response. Thank you. ' answered with 'The hematoma of the leg is not an indication of this medication, the medication dose was reduced because he had a hematoma on his leg. ' (Site from DM).	Diana Bahena (b) (4) (b) (4)	08 Mar 2021 20:40:51
User closed query 'Per DM CLR: Was the dose of this medication increased from 25 mg to 50 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:28:38
User opened query 'Per CDM re-query: Thank you for the response. Please confirm the recorded indication is correct else update the indication to "HEMATOMA OF THE R LEG" if appropriate per response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:28:36
Query 'Per DM CLR: Was the dose of this medication increased from 25 mg to 50 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose.' answered with 'The dose was lowered from 5 to 2.5 due to hematoma in leg, as describes in AE's' (Site from DM).	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:34:18

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US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Was the dose of this medication increased from 25 mg to 50 mg because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for increased dose.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 07:03:54
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'cerebrovascular disease and atrial fibrillation'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '2.5'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'twice daily (BID)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:24:29
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '16 Nov 2020' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	30 Nov 2020 20:20:45
User entered '17 Nov 2020'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '2'	System	30 Nov 2020 20:24:29
User entered '1'	System	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (7)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Nov 2020 20:46:03

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
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)	25 Nov 2020 20:49:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Nov 2020 20:49:51
Data point term sent to Coder	System	25 Nov 2020 20:47:42
User entered 'metoprolol xl'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

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US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'atrial fibrillation'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '50'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

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US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'mg (mg)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'once daily (QD)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Oral (ORAL)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '18 Nov 2020'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '0'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
Signature has been broken.	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:04:21
User entered 'No (N)' reason for change: New Information	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:04:21
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
Signature has been broken.	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:04:21
User entered '01 Mar 2021' reason for change: New Information	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:04:21
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'No (N)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User entered '1'	System	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User entered '1'	System	25 Nov 2020 20:47:33

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (8)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 10:54:39
User entered '804 (804)'	System	25 Nov 2020 20:47:33

FDA-CBER-2022-1614-2448351

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: IRON - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:30:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	07 Apr 2021 10:30:29
Data point term sent to Coder	System	31 Mar 2021 19:06:09
User entered 'Iron'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

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US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Prophylaxis

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Low Hemogloblin'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

FDA-CBER-2022-1614-2448354

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Dose per administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '27'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Dose unit

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'mg (mg)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered empty.	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

FDA-CBER-2022-1614-2448357

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Frequency

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'once daily (QD)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered empty.	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Route of administration

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Oral (ORAL)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered empty.	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Start date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '11 Nov 2020'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered '0'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Ongoing?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'Yes (Y)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
If not Ongoing, End date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered empty.	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Was this medication taken for solicited event?

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Apr 2021 16:23:39
User entered 'No (N)'	Lorna Sanchez McCann (b) (4)	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Separate Dosage Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Unit Number (derived)

Audit	User	Time (GMT)
User entered '1'	System	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (9)
Generated On: 10 Jun 2021 07:56:52
Interval Dosage Definition (derived)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Mar 2021 19:05:20

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures Summary
Generated On: 10 Jun 2021 07:56:52
Were any concomitant procedures performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:15:09
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:32
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Yes (Y)' reason for change: New Information	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:51:56
User entered 'No (N)' reason for change: Data Entry Error	Marla Schwarber (b) (4) (b) (4)	04 Nov 2020 20:19:09
User entered 'Yes (Y)'	Marla Schwarber (b) (4) (b) (4)	08 Sep 2020 14:42:08

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:58:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '13 Nov 2020'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:52:49

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US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:58:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'arterial angiogram with embolization'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:52:49

FDA-CBER-2022-1614-2448372

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:58:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Adverse Event (AE)'	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:52:49

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (7)
Generated On: 10 Jun 2021 07:56:52
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 00:58:24
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Marla Schwarber (b) (4) (b) (4)	25 Nov 2020 20:52:49

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '11 Nov 2020'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:22:31

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Colonoscopy'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:22:31

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered 'Adverse Event (AE)'	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:22:31

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (8)
Generated On: 10 Jun 2021 07:56:52
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:31
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	25 Nov 2020 21:22:31

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered '11 Nov 2020'	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:39:18

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'CT Right Lower extremity'	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:39:18

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US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'Adverse Event (AE)'	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:39:18

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (9)
Generated On: 10 Jun 2021 07:56:52
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:35
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered empty.	Diana Bahena (b) (4) (b) (4)	23 Feb 2021 16:39:18

FDA-CBER-2022-1614-2448382

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered '10 Nov 2020'	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:29:00

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered '3 units of PRBC infusion'	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:29:00

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered 'Adverse Event (AE)'	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:29:00

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (10)
Generated On: 10 Jun 2021 07:56:52
If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:51:37
DataPoint Verified.	(b) (4), (b) (6)	13 Apr 2021 16:23:38
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered empty.	Diana Bahena (b) (4) (b) (4)	05 Mar 2021 20:29:00

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery date *(dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '24 Apr 2021'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:48:49

FDA-CBER-2022-1614-2448387

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 07:56:52
Procedure/Surgery

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Chest tube placement to drain pleural effusion'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:48:49

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 07:56:52
Indication

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered 'Adverse Event (AE)'	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:48:49

US3492078
Folder: Concomitant Procedures (1)
Form: Concomitant Procedures (11)
Generated On: 10 Jun 2021 07:56:52
If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered empty.	Andrea Wendrow (b) (4) (b) (4)	29 Apr 2021 22:48:49

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448398

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448402

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:07:40
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Feb 2021 20:50:17
User entered '4'	System	23 Feb 2021 20:50:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '3'	System	04 Feb 2021 14:01:32
User entered '2'	System	30 Nov 2020 21:07:50
User entered '1'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448409

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448412

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448414

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448420

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:07:40
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Feb 2021 20:50:17
User entered '4'	System	23 Feb 2021 20:50:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '3'	System	04 Feb 2021 14:01:32
User entered '2'	System	30 Nov 2020 21:07:50
User entered '1'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 07:56:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
User entered '23/Nov/2020 20:08'	System	23 Nov 2020 20:08:16

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:56:52

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) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:07:40
User entered '1'	(b) (4), (b) (6)	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448430

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448432

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448437

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:07:40
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Feb 2021 20:50:17
User entered '4'	System	23 Feb 2021 20:50:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '3'	System	04 Feb 2021 14:01:32
User entered '2'	System	30 Nov 2020 21:07:50
User entered '1'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (2)
Generated On: 10 Jun 2021 07:56:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
User entered '30/Nov/2020 21:07'	System	30 Nov 2020 21:07:50

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 07:56:52

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) (b) (4)	15 Feb 2021 03:38:48
Reviewed for Safety.	(b) (4), (b) (6)	04 Feb 2021 14:01:01
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
User entered '1'	(b) (4), (b) (6)	30 Nov 2020 21:07:50

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448450

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448456

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:07:40
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Feb 2021 20:50:17
User entered '4'	System	23 Feb 2021 20:50:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '3'	System	04 Feb 2021 14:01:32
User entered '2'	System	30 Nov 2020 21:07:50
User entered '1'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (3)
Generated On: 10 Jun 2021 07:56:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '04/Feb/2021 14:01'	System	04 Feb 2021 14:01:32

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 07:56:52

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)	31 Mar 2021 15:54:29
Reviewed for Safety.	(b) (4), (b) (6)	23 Feb 2021 20:50:03
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
User entered '1'	(b) (4), (b) (6)	04 Feb 2021 14:01:32

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'USA-US101-2020-MRNA-1273-P301000006'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448461

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Yes (Y)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'No (N)'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448468

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Richard'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Novak'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '808 S. Wood St'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448471

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'Chicago'	System	23 Nov 2020 14:23:42

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered 'IL'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448473

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	23 Nov 2020 20:08:09
User entered '60612'	System	23 Nov 2020 14:23:42

FDA-CBER-2022-1614-2448474

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 18:36:31
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 21:07:40
User entered 'US'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
Signature has been broken.	System	23 Feb 2021 20:50:17
User entered '4'	System	23 Feb 2021 20:50:17
User signature succeeded.	Richard Novak (b) (4) (b) (4)	15 Feb 2021 03:38:48
User entered '3'	System	04 Feb 2021 14:01:32
User entered '2'	System	30 Nov 2020 21:07:50
User entered '1'	System	23 Nov 2020 20:08:16

US3492078
Folder: SAE USA-US101-2020-MRNA-1273-P301000006
Form: Safety Report Form (4)
Generated On: 10 Jun 2021 07:56:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	31 Mar 2021 15:54:29
User signature succeeded.	Richard Novak (b) (4)	26 Mar 2021 01:41:47
User entered '23/Feb/2021 14:50'	(b) (4) System	23 Feb 2021 20:50:17

US3492078

Folder: SAE USA-US101-2020-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 07:56:52

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)	31 Mar 2021 15:54:29
User signature succeeded.	Richard Novak (b) (4) (b) (4)	26 Mar 2021 01:41:47
User entered '1'	(b) (4), (b) (6)	23 Feb 2021 20:50:17

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'USA-US101-2021-MRNA-1273-P301000012'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Yes (Y)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Yes (Y)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Richard'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Novak'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered '808 S. Wood St'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Chicago'	System	30 Apr 2021 15:27:26

FDA-CBER-2022-1614-2448490

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'IL'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered '60612'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'US'	System	30 Apr 2021 15:27:52

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:27:52

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
SAEID

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'USA-US101-2021-MRNA-1273-P301000012'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Yes (Y)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Death

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Life threatening

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

FDA-CBER-2022-1614-2448498

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Yes (Y)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Congenital anomaly or birth defect

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Other medically important event

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'No (N)'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's First Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Richard'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator's Last Name

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Novak'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered '808 S. Wood St'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'Chicago'	System	30 Apr 2021 15:27:26

FDA-CBER-2022-1614-2448506

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'IL'	System	30 Apr 2021 15:27:26

FDA-CBER-2022-1614-2448507

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Site Address: Postal Code

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered '60612'	System	30 Apr 2021 15:27:26

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
Investigator Country

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered 'US'	System	30 Apr 2021 15:27:52

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form
Generated On: 10 Jun 2021 07:56:52
E2B Transmit Flag (Derived/Hidden)

Audit	User	Time (GMT)
User entered '1'	System	30 Apr 2021 15:27:52

US3492078
Folder: SAE USA-US101-2021-MRNA-1273-P301000012
Form: Safety Report Form (1)
Generated On: 10 Jun 2021 07:56:52
Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Richard Novak (b) (4) (b) (4)	30 Apr 2021 21:45:15
User entered '30/Apr/2021 11:27'	System	30 Apr 2021 15:27:52

US3492078

Folder: SAE USA-US101-2021-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 07:56:52

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) (b) (4)	30 Apr 2021 21:45:15
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 15:27:56
User entered '1'	(b) (4), (b) (6)	30 Apr 2021 15:27:52