

US3192614 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:45:33

All time stamps listed in this document are displayed in GMT

US3192614

Form: Participant Creation

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

[Participant ID](#)

US3192614

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

US3192614

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 14 Feb 2021 03:14:54

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Date of Informed Consent (<i>dd MMM yyyy</i>)	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 14 Feb 2021 03:14:54

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 14 Feb 2021 03:14:54

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 14 Feb 2021 03:14:54

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

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN FEB 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2011
Start Year (derived)	2011
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	HIGH CHOLESTEROL
Start date (dd MMM yyyy)	UN FEB 2011
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	NON-ST SEGMENT ELEVATION MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	HIGH BLOOD PRESSURE
Start date (dd MMM yyyy)	UN FEB 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	ANXIETY
Start date (dd MMM yyyy)	UN FEB 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	ATTENTION DEFICIT DISORDER
Start date (dd MMM yyyy)	UN FEB 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	TACHYCARDIA
Start date (dd MMM yyyy)	UN APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Condition	VENTRICULAR FIBRILLATION
Start date (dd MMM yyyy)	UN APR 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	17:45 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 17:45
Height (<i>xxx.x</i>)	59 in
Weight (<i>xxx.x</i>)	239 lb
BMI (<i>xxx.x</i>)	48.37308 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 14 Feb 2021 03:14:54

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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) 14 Feb 2021 03:14:54

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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)	True
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145541

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	17:45 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 17:45
Temperature (xxx.x)	98.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	18:56 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 18:56
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	171 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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) 31 AUG 2020

What was the treatment time? (00:00-23:59) 18:23 (24 HR)

Treatment Date and Time (derived) 31 AUG 2020 18:23

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 AUG 2020
Collection time (00:00-23:59)	18:08 (24 HR)
Collection date and time (derived)	31 AUG 2020 18:08

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:57	31 AUG 2020 17:57
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 31 AUG 2020 18:54

PC Open Date & Time 31 AUG 2020 18:43

PC Close Date & Time 31 AUG 2020 21:13

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.7 °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	01 SEP 2020 10:03
PC Open Date & Time	31 AUG 2020 22:08
PC Close Date & Time	01 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 18:22

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

98.7 °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

02 SEP 2020 20:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 20:30

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 SEP 2020 20:46

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 20:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 AUG 2020 18:54

PC Open Date & Time

31 AUG 2020 18:43

PC Close Date & Time

31 AUG 2020 21:13

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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)**

300

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 - **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

01 SEP 2020 10:06

PC Open Date & Time

31 AUG 2020 22:08

PC Close Date & Time

01 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 SEP 2020 18:23

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 SEP 2020 20:50

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 20:32

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 20:31

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:46

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 20:31

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 18:56
PC Open Date & Time	31 AUG 2020 18:43
PC Close Date & Time	31 AUG 2020 21:13

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 10:07
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PC Open Date & Time	31 AUG 2020 22:08
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PC Close Date & Time	01 SEP 2020 11:59
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US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 18:23
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

58 of 2515

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:51
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:33
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 20:31
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:47
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

66 of 2515

EAB) (1725)

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 20:32
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3192614

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 04:05:02

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 04:05:02

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 15:50
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 SEP 2020
Time of assessment (00:00-23:59)	17:06 (24 HR)
Vital Signs Date and Time (derived)	29 SEP 2020 17:06
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	154 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3192614

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 SEP 2020

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

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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) 29 SEP 2020

What was the treatment time? (00:00-23:59) 16:36 (24 HR)

Treatment Date and Time (derived) 29 SEP 2020 16:36

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

US3192614

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 SEP 2020
Collection time (00:00-23:59)	16:27 (24 HR)
Collection date and time (derived)	29 SEP 2020 16:27

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Collection date (dd MMM yyyy)			29 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:29	29 SEP 2020 16:29
Nasopharyngeal Swab 2	No		

US3192614

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 17:05

PC Open Date & Time

29 SEP 2020 16:56

PC Close Date & Time

29 SEP 2020 19:26

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.6 °F

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

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

PC Time Stamp	29 SEP 2020 20:37
PC Open Date & Time	29 SEP 2020 20:21
PC Close Date & Time	30 SEP 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

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

30 SEP 2020 19:12

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 OCT 2020 20:31

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 OCT 2020 18:13

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

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

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 OCT 2020 19:32

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 OCT 2020 19:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 OCT 2020 21:36

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 17:06

PC Open Date & Time

29 SEP 2020 16:56

PC Close Date & Time

29 SEP 2020 19:26

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

29 SEP 2020 20:37

PC Open Date & Time

29 SEP 2020 20:21

PC Close Date & Time

30 SEP 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

30 SEP 2020 19:14

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

01 OCT 2020 20:31

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

02 OCT 2020 18:14

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

03 OCT 2020 19:31

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 OCT 2020 19:31

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

05 OCT 2020 21:37

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 17:06
PC Open Date & Time	29 SEP 2020 16:56
PC Close Date & Time	29 SEP 2020 19:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 20:38
PC Open Date & Time	29 SEP 2020 20:21
PC Close Date & Time	30 SEP 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 19:14
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	01 OCT 2020 20:31
PC Open Date & Time	01 OCT 2020 12:00
PC Close Date & Time	02 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 ☒

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106 of 2515

EAB) (1725)

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 18:13
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 19:31
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 19:31
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 ☒

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

Yes <input type="checkbox"/>	
PC Time stamp	05 OCT 2020 21:37
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☐

FATIGUE

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 06 OCT 2020 21:27

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your

None ☒

FATIGUE

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time Stamp 08 OCT 2020 01:38

PC Open Date & Time 07 OCT 2020 12:00

PC Close Date & Time 08 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 06 OCT 2020 21:27

PC Open Date & Time 06 OCT 2020 12:00

PC Close Date & Time 07 OCT 2020 11:59

US3192614

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 21:27
PC Open Date & Time	06 OCT 2020 12:00
PC Close Date & Time	07 OCT 2020 11:59

US3192614

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 OCT 2020
Time of assessment (00:00-23:59)	15:58 (24 HR)
Vital Signs Date and Time (derived)	29 OCT 2020 15:58
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	86 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	162 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192614

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 OCT 2020

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

US3192614

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 OCT 2020
Collection time (00:00-23:59)	16:16 (24 HR)
Collection date and time (derived)	29 OCT 2020 16:16

US3192614

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 14 Feb 2021 03:14:54

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Close Date & Time

04 NOV 2020 23:59

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Close Date & Time

11 NOV 2020 23:59

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

18 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

25 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

29 NOV 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

02 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

09 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

16 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 DEC 2020 13:37:09
Patient Cloud Open Date & Time	23 DEC 2020 00:01
Patient Cloud Close Date & Time	27 DEC 2020 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 JAN 2021 12:00:48
Patient Cloud Open Date & Time	30 DEC 2020 00:01
Patient Cloud Close Date & Time	03 JAN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

08 JAN 2021 20:45:17

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

14 JAN 2021 07:43:36

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

20 JAN 2021 09:14:25

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

07 FEB 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 FEB 2021 16:33:10
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

19 FEB 2021 14:13:19

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 FEB 2021 13:18:04
Patient Cloud Open Date & Time	24 FEB 2021 00:01
Patient Cloud Close Date & Time	28 FEB 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 MAR 2021 00:01
Patient Cloud Close Date & Time	07 MAR 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

11 MAR 2021 15:12:35

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

19 MAR 2021 17:14:59

Patient Cloud Open Date & Time

17 MAR 2021 00:01

Patient Cloud Close Date & Time

21 MAR 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

24 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

31 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

11 APR 2021 16:44:02

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

28 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

05 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

19 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

26 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

02 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

09 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

16 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

30 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 313

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

21 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2021 00:01
Patient Cloud Close Date & Time	15 AUG 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Open Date & Time	25 AUG 2021 00:01
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Patient Cloud Close Date & Time	29 AUG 2021 23:59
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US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 383

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

15 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 390

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

22 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2021 00:01
Patient Cloud Close Date & Time	10 OCT 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Open Date & Time	13 OCT 2021 00:01
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Patient Cloud Close Date & Time	17 OCT 2021 23:59
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US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Open Date & Time	20 OCT 2021 00:01
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Patient Cloud Close Date & Time	24 OCT 2021 23:59
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US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 439

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

17 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

21 NOV 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 453

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

08 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

12 DEC 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 474

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 DEC 2021 00:01
Patient Cloud Close Date & Time	26 DEC 2021 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

29 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JAN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

05 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JAN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 502

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

12 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JAN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

19 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JAN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JAN 2022 00:01
Patient Cloud Close Date & Time	30 JAN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 523

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

09 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 537

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

16 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

20 FEB 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 544

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 551

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

02 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

09 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

23 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 APR 2022 00:01
Patient Cloud Close Date & Time	17 APR 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

27 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAY 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

04 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

08 MAY 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

11 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAY 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

18 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAY 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

25 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAY 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

22 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUN 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 677

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

13 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUL 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

20 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JUL 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

03 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

07 AUG 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 AUG 2022 00:01
Patient Cloud Close Date & Time	14 AUG 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

17 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

21 AUG 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

Patient Cloud Open Date & Time	24 AUG 2022 00:01
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Patient Cloud Close Date & Time	28 AUG 2022 23:59
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US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

14 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

18 SEP 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

21 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

25 SEP 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 OCT 2022 00:01
Patient Cloud Close Date & Time	09 OCT 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

12 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

16 OCT 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 OCT 2022 00:01
Patient Cloud Close Date & Time	30 OCT 2022 23:59

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

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

[Patient Cloud Open Date & Time](#)

02 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

06 NOV 2022 23:59

US3192614

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:45:33

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		11 MAR 2021 15:12:17

US3192614

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 09 Mar 2021 17:30:13

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 09 Mar 2021 17:30:13

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

31 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

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 _____

US3192614

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

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 _____

US3192614

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 12 Apr 2021 18:00:02

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	8 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 12 Apr 2021 18:00:02

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	8 APR 2021
Time of assessment (<i>00:00-23:59</i>)	15:04 (24 HR)
Vital Signs Date and Time (derived)	8 APR 2021 15:04
Temperature (<i>xxx.x</i>)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	88 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	178 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192614

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 12 Apr 2021 18:00:02

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3192614

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Apr 2021 18:00:02

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	8 APR 2021
Collection time (00:00-23:59)	15:13 (24 HR)
Collection date and time (derived)	8 APR 2021 15:13

US3192614

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 12 Apr 2021 18:00:02

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3192614

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:45:33

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3192614

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

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

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

Visit date (dd MMM yyyy)	14 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3192614

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

Form: Unblinding

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Date of updated informed consent (<i>dd MMM yyyy</i>)	14 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	14 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3192614

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Height	69 in
Weight	226.2 lb
BMI (xxx.x)	33.47375

US3192614

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Height	69 in
Weight	226.2 lb
BMI (xxx.x)	33.47375
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	15:14 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 15:14
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	165 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3192614

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Height	69 in
Weight	226.2 lb
BMI (xxx.x)	33.47375
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	14 JAN 2021
Time of assessment (00:00-23:59)	16:32 (24 HR)
Vital Signs Date and Time (derived)	14 JAN 2021 16:32
Temperature (xxx.x)	99.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3192614

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

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 JAN 2021

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

US3192614

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

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 01:24:38

Generated On: 09 Jun 2021 15:45:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 14 JAN 2021

What was the treatment time? (00:00-23:59) 16:02 (24 HR)

Treatment Date and Time (derived) 14 JAN 2021 16:02

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00-23:59)	15:27 (24 HR)
Collection date and time (derived)	14 JAN 2021 15:27

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	15:28
Collection Date and Time (derived)	14 JAN 2021 15:28

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:38

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3192614

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 15:50
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	157 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	11 FEB 2021
Time of assessment (00:00-23:59)	16:35 (24 HR)
Vital Signs Date and Time (derived)	11 FEB 2021 16:35
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	166 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3192614

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 FEB 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3192614

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 11 FEB 2021

What was the treatment time? (00:00-23:59) 16:05 (24 HR)

Treatment Date and Time (derived) 11 FEB 2021 16:05

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

US3192614

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3192614

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 01:24:39

Generated On: 09 Jun 2021 15:45:33

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3192614

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	11 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	16:18 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 16:18
Temperature (<i>xxx.x</i>)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	63 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	171 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3192614

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3192614

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	16:28 (24 HR)
Collection date and time (derived)	11 MAR 2021 16:28

US3192614

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 28 Mar 2021 18:40:41

Generated On: 09 Jun 2021 15:45:33

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3192614

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

AEID	USA-US097-2020-MRNA-1273-P30 1000002
Adverse event	PERICARDITIS EFFUSION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	15 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

US3192614

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

PATIENT REPORTED HE WAS
HAVING CHEST PAIN, STARTED
ON 11SEP2020, WAS SEEN IN
THE ER ON 14SEP2020 AND
DIAGNOSED WITH
PERICARDIAL EFFUSION,
STATED IT WAS DRAINED,
KEPT FOR OBSERVATION
OVERNIGHT. CON MEDS
WEREN'T CHANGED OR
AMENDED.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

AEID

Adverse event

SORE ARM POST INJECTION

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)

12 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 FEB 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 08 Apr 2021 12:36:57

Generated On: 09 Jun 2021 15:45:33

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication VENTRICULAR
FIBRILLATION/TACHYCARDIA

Dose per administration 200

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication GLIPIZIDE ER

Prophylaxis Yes ☐
No ☒

Indication DIABETES

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 0.4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

Dose per administration 80

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication LOSARTAN/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 100/125

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication OXYCONTIM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 30

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication ALPRAZOLAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 0.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 30

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES

Dose per administration 1000

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication DULOXETINE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 60

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication COREG

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 12.5

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2011	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication NERVE PAIN

Dose per administration 300

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

6X A DAY

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication SILDENAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication TIZANIDINE

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASM

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☒
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication PAIN ON INJECTION SITE

Dose per administration 400

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	31 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 01:24:37

Generated On: 09 Jun 2021 15:45:33

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3192614

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:45:33

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

US3192614

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:45:33

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 ☐

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	17/SEP/2020 11:52
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.	True

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	24/SEP/2020 10:00
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

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	07/OCT/2020 14:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	12/OCT/2020 14:28
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

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	02/NOV/2020 22:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	13/NOV/2020 11:06
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

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/NOV/2020 14:29
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

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Data signed: (b) (4) 08 Apr 2021 19:45:03

Generated On: 09 Jun 2021 15:45:33

SAEID	USA-US097-2020-MRNA-1273-P301000002
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JOHN
Investigator's Last Name	MCGETTIGAN
Site Address: Street	5390 E. ERICKSON DRIVE
Site Address: City	TUCSON
Site Address: State	AZ
Site Address: Postal Code	85712
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/APR/2021 11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3192614 (Prod: Quality of Life Medical and Research Center - Hunt - PPDS)

US3192614

Form: Participant Creation

Generated On: 09 Jun 2021 15:45:33

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'US3192614'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 00:34:25

US3192614

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:58:23

US3192614

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 00:34:26

US3192614

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Clinic (Clinic)'	maggie Tono (b) (4)	06 Sep 2020 15:58:23

US3192614

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'SCRN'	System	06 Sep 2020 15:58:23

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User closed query 'Per CDM: Data is required. Please complete this form' (Site from DM).	(b) (4)	
Query 'Per CDM: Data is required. Please complete this form' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Sep 2020 12:05:36
User opened query 'Per CDM: Data is required. Please complete this form' (Site from DM).	maggie Tono (b) (4)	06 Sep 2020 15:59:08
User entered (b) (6) 1959'	(b) (4)	
	(b) (4), (b) (6)	03 Sep 2020 11:51:43
	RWS_ENDPOINT	01 Sep 2020 00:34:28
	ENDPOINT (b) (4)	

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '60'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'YEARS'	System	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '60'	System	01 Sep 2020 01:35:05

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Male (M)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'I'	maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:45:33

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:01

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	(b) (4)	
	Saysamone Banks (b) (4)	01 Sep 2020 01:35:05
	(b) (4)	

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Aug 2020'	System	01 Sep 2020 01:35:05

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2020'	System	01 Sep 2020 01:35:05

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Amendment 3 (3)'	Saysamone Banks (b) (4)	01 Sep 2020 01:35:05

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	01 Sep 2020 01:35:05
	(b) (4)	

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Saysamone Banks (b) (4)	01 Sep 2020 01:35:05

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	01 Sep 2020 01:35:05
	(b) (4)	

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	(b) (4)	
	Saysamone Banks (b) (4)	01 Sep 2020 01:35:05
	(b) (4)	

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 00:34:26

US3192614

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:45:33

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'I'	System	01 Sep 2020 01:35:12

US3192614

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:45:33

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	01 Sep 2020 01:35:12

US3192614

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:45:33

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 15:52:18

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Diabetes mellitus, LLT: Diabetes - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:54:36
Data point term sent to Coder	System	06 Sep 2020 15:53:23
User entered 'diabetes'	maggie Tono (b) (4)	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Jan 2015'	System	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2015'	System	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:52:50

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 15:54:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:54:36
Data point term sent to Coder	System	06 Sep 2020 15:53:25
User entered 'hypertension'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2011'	maggie Tono (b) (4)	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2011'	System	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2011'	System	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:53:07

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Investigations, HLGTT: Lipid analyses, HLT: Cholesterol analyses, PT: Blood cholesterol increased, LLT: High cholesterol - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:55:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:55:37
Data point term sent to Coder	System	06 Sep 2020 15:54:26
User entered 'high cholesterol'	maggie Tono (b) (4)	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2011'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2011'	System	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2011'	System	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:53:27

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	06 Sep 2020 15:55:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:55:37
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 15:54:26
User entered 'Atrial fibrillation'	maggie Tono (b) (4)	06 Sep 2020 15:54:03
	(b) (4)	

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Apr 2018'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Apr 2018'	System	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:54:03

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid disorders NEC, PT: Goitre, LLT: Goiter - version MedDRA\\23.0.	(b) (4)	
	Coder Import (b) (4)	06 Sep 2020 15:56:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:56:37
	(b) (4)	
Data point term sent to Coder	System	06 Sep 2020 15:55:26
User entered 'Goiter'	maggie Tono (b) (4)	06 Sep 2020 15:54:42
	(b) (4)	

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2010'	maggie Tono (b) (4)	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'I'	maggie Tono (b) (4)	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2010'	System	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2010'	System	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:54:42

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:56:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:56:37
Data point term sent to Coder	System	06 Sep 2020 15:55:27
User entered 'osteoarthritis'	maggie Tono (b) (4)	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2010'	maggie Tono (b) (4)	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2010'	System	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2010'	System	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:55:04

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Cardiac disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non ST segment elevation myocardial infarction - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:39:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	25 Nov 2020 00:39:37
Data point term sent to Coder	System	06 Sep 2020 15:56:27
User entered 'non-ST segment elevation myocardial infarction'	maggie Tono (b) (4)	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Apr 2018'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Apr 2018'	System	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:55:37

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:57:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	06 Sep 2020 15:57:37
Data point term sent to Coder	System	06 Sep 2020 15:56:29
User entered 'high blood pressure'	maggie Tono (b) (4)	06 Sep 2020 15:55:53
	(b) (4)	

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2018'	maggie Tono (b) (4)	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2018'	System	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	06 Sep 2020 15:55:53

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:40:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:40:04
Data point term sent to Coder	System	31 Oct 2020 00:39:25
User entered 'Anxiety'	Yvonne De Los Reyes	31 Oct 2020 00:38:54
	(b) (4)	

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2018'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2018'	System	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:38:54

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Psychiatric disorders, HLG: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:41:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:41:04
Data point term sent to Coder	System	31 Oct 2020 00:40:26
User entered 'Attention Deficit Disorder'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Feb 2018'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Feb 2018'	System	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:40:03

US3192614

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:40:03

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Rate and rhythm disorders NEC, PT: Tachycardia, LLT: Tachycardia - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:47:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:47:07
Data point term sent to Coder	System	31 Oct 2020 00:46:28
User entered 'Tachycardia'	Yvonne De Los Reyes	31 Oct 2020 00:45:33
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Apr 2018'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:45:33

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:45:33

US3192614

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Yvonne De Los Reyes	31 Oct 2020 00:46:06
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).	(b) (4)	
	System	31 Oct 2020 00:45:40
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes	31 Oct 2020 00:45:40
	(b) (4)	
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	31 Oct 2020 00:45:33
User entered 'Yes (Y)'	Yvonne De Los Reyes	31 Oct 2020 00:45:33
	(b) (4)	

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Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty; reason for change Data Entry Error	(b) (4)	31 Oct 2020 00:46:06
User entered 'un Apr 2018'	Yvonne De Los Reyes	31 Oct 2020 00:45:33
	(b) (4)	

US3192614

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:45:33

US3192614

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Apr 2018'	System	31 Oct 2020 00:45:33

US3192614

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	31 Oct 2020 00:45:33

US3192614

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:46:06
User entered 'Apr 2018'	System	31 Oct 2020 00:45:33

US3192614

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:46:06
User entered '2018'	System	31 Oct 2020 00:45:33

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Ventricular arrhythmias and cardiac arrest, PT: Ventricular fibrillation, LLT: Ventricular fibrillation - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	31 Oct 2020 00:48:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:48:07
Data point term sent to Coder	System	31 Oct 2020 00:47:29
User entered 'Ventricular Fibrillation'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Apr 2018'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Apr 2018'	System	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2018'	System	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	31 Oct 2020 00:46:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Sensory abnormalities NEC, PT: Neuralgia, LLT: Nerve pain - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:33:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:33:36
Data point term sent to Coder	System	12 Nov 2020 21:33:20
User entered 'Nerve Pain'	Amanda Hermosillo	12 Nov 2020 21:32:34
	(b) (4)	

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'UN Jan 2015'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Amanda Hermosillo (b) (4)	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Jan 2015'	System	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2015'	System	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	12 Nov 2020 21:32:34

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:36:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:36:35
Data point term sent to Coder	System	12 Nov 2020 21:35:23
User entered 'Erectile Dysfunction'	Amanda Hermosillo	12 Nov 2020 21:34:32
	(b) (4)	

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Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'UN Jan 2015'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Jan 2015'	System	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2015'	System	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	12 Nov 2020 21:34:32

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Muscle spasms - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:36:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:36:37
Data point term sent to Coder	System	12 Nov 2020 21:36:25
User entered 'Muscle Spasms'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'un Jan 2015'	Amanda Hermosillo	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Amanda Hermosillo	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	Amanda Hermosillo (b) (4)	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'Jan 2015'	System	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '2015'	System	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:45:33

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered empty.	System	12 Nov 2020 21:35:59

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '17:45'	maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '31 Aug 2020 17:45'	System	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '59' in	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25
DataPoint set to visible.	(b) (4) System	01 Sep 2020 01:35:12

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '239' lb	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25
DataPoint set to visible.	(b) (4) System	01 Sep 2020 01:35:12

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '48.37308'	System	06 Sep 2020 16:01:25
DataPoint set to visible.	System	01 Sep 2020 01:35:12

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'kg/m2'	System	06 Sep 2020 16:01:25
DataPoint set to visible.	System	01 Sep 2020 01:35:12

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'bpm'	System	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'breaths/min'	System	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'mmHg'	System	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	(b) (4) maggie Tono (b) (4)	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'mmHg'	System	06 Sep 2020 16:01:25

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57

US3192614

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57

US3192614

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:00:43

US3192614

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	maggie Tono (b) (4)	06 Sep 2020 16:00:43

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'I'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '0'	(b) (4) maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:45:33

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 15:59:54

US3192614

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:01:40

US3192614

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	maggie Tono (b) (4)	06 Sep 2020 16:01:40

US3192614

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Clinic (Clinic)'	maggie Tono (b) (4)	06 Sep 2020 16:01:40

US3192614

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'VISIT1'	System	06 Sep 2020 16:01:40

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 01:14:31

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '145541'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 01:14:31

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	01 Sep 2020 01:14:31

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User closed query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Sep 2020 12:05:13
Query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' answered with 'no' (Site from DM).	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:00:29
User entered 'No (N)'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:00:23
User opened query 'Per CDM: Please complete this section of the form (a required response (Yes or No) is needed for each), otherwise explain.' (Site from DM).	(b) (4), (b) (6)	03 Sep 2020 14:48:39

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 16:00:23

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 16:00:23

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:00:23

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 16:00:23

US3192614

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:45:33

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 15:01:36
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'Field completed' (Site from DM).	Saysamone Banks (b) (4)	02 Dec 2020 17:21:13
User entered 'No (N)'	Saysamone Banks (b) (4)	02 Dec 2020 17:21:09
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 05:43:54
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 08:51:19
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:51:18

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User accepted default value 'Pre-Dose (PREDOSE)'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '17:45'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered '31 Aug 2020 17:45'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '98.7' F	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Oral (Oral)'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '64'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'bpm'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '18'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'breaths/min'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
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)	16 Sep 2020 13:18:32
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 9 sept 2020' (Site from System).	maggie Tono (b) (4) (b) (4)	10 Sep 2020 20:55:05
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	06 Sep 2020 16:04:20
User entered '158'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'mmHg'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '72'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'mmHg'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered missing code ND - Not Done.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User accepted default value 'Post-Dose (POSTDOSE)'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '18:56'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered '31 Aug 2020 18:56'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '97.7' F	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Oral (Oral)'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '66'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'bpm'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '18'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'breaths/min'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
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)	16 Sep 2020 13:18:38
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 9 sept 2020' (Site from System).	maggie Tono (b) (4) (b) (4)	10 Sep 2020 20:54:40
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	06 Sep 2020 16:04:20
User entered '171'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'mmHg'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '85'	maggie Tono (b) (4)	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'mmHg'	System	06 Sep 2020 16:04:20

US3192614

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 16:01:51

US3192614

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 16:01:51

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4)	
	Saysamone Banks (b) (4)	01 Sep 2020 01:35:34
	(b) (4)	

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Saysamone Banks (b) (4)	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4)	
	Saysamone Banks (b) (4)	01 Sep 2020 01:35:34
	(b) (4)	

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	Saysamone Banks (b) (4)	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '18:23'	Saysamone Banks (b) (4)	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered '31 Aug 2020 18:23'	System	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Left Arm (LEFT ARM)'	Saysamone Banks (b) (4)	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'ONCE'	System	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 01:35:34

US3192614

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:02:43

US3192614

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	maggie Tono (b) (4)	06 Sep 2020 16:02:43

US3192614

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '18:08'	maggie Tono (b) (4)	06 Sep 2020 16:02:43

US3192614

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered '31 Aug 2020 18:08'	System	06 Sep 2020 16:02:43

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '31 Aug 2020'	maggie Tono (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '17:57'	maggie Tono (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered '31 Aug 2020 17:57'	System	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	maggie Tono (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	maggie Tono (b) (4)	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered empty.	System	06 Sep 2020 16:02:29

US3192614

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 16:01:55

US3192614

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	06 Sep 2020 16:01:55

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:52:51', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3e7d4230-9f58-449f-bf3c-6db7faa7bf20'	System	01 Sep 2020 01:53:51
User entered 'Yes (Y)'	System	01 Sep 2020 01:53:51

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:53:24', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3e7d4230-9f58-449f-bf3c-6db7faa7bf20' User entered '97.7'	System	01 Sep 2020 01:53:51
	System	01 Sep 2020 01:53:51

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:53:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3e7d4230-9f58-449f-bf3c-6db7faa7bf20'	System	01 Sep 2020 01:53:51
User entered 'Yes (Y)'	System	01 Sep 2020 01:53:51

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACTED PATIENT WHO REPORTS TAKING IBUPROFEN 400 MG FOR PAIN. PAIN WAS RESOLVED ON THIS DAY.' (Site from System).		01 Oct 2020 17:30:32
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Crystal Mata (b) (4)	26 Sep 2020 17:42:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:53:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3e7d4230-9f58-449f-bf3c-6db7faa7bf20'	(b) (4)	
User entered '1'	System	01 Sep 2020 01:53:51
	System	01 Sep 2020 01:53:51
	System	01 Sep 2020 01:53:51

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:53:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3e7d4230-9f58-449f-bf3c-6db7faa7bf20'	System	01 Sep 2020 01:53:51
User entered '0'	System	01 Sep 2020 01:53:51

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:54:01', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3e7d4230-9f58-449f-bf3c-6db7faa7bf20'	System	01 Sep 2020 01:53:51
User entered '31 Aug 2020 18:54'	System	01 Sep 2020 01:53:51

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 18:43'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 21:13'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:03:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b1a67cf4-f7d7-4639-9911-b77dbaf99914'	System	01 Sep 2020 17:03:42
User entered 'Yes (Y)'	System	01 Sep 2020 17:03:42

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:03:37', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b1a67cf4-f7d7-4639-9911-b77dbaf99914' User entered '98.7'	System	01 Sep 2020 17:03:42
	System	01 Sep 2020 17:03:42

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:03:45', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b1a67cf4-f7d7-4639-9911-b77dbaf99914'	System	01 Sep 2020 17:03:42
User entered 'No (N)'	System	01 Sep 2020 17:03:42

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:03:50', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b1a67cf4-f7d7-4639-9911-b77dbaf99914'	System	01 Sep 2020 17:03:42
User entered '01 Sep 2020 10:03'	System	01 Sep 2020 17:03:42

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 22:08'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 2'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:11', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd0b8317c-db4e-46ca-8953-48a8fd8ebf41'	System	02 Sep 2020 01:22:17
User entered 'Yes (Y)'	System	02 Sep 2020 01:22:17

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:17', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd0b8317c-db4e-46ca-8953-48a8fd8ebf41'	System	02 Sep 2020 01:22:17
User entered '98.6'	System	02 Sep 2020 01:22:17

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:23', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd0b8317c-db4e-46ca-8953-48a8fd8ebf41'	System	02 Sep 2020 01:22:17
User entered 'No (N)'	System	02 Sep 2020 01:22:17

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:28', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd0b8317c-db4e-46ca-8953-48a8fd8ebf41'	System	02 Sep 2020 01:22:17
User entered '01 Sep 2020 18:22'	System	02 Sep 2020 01:22:17

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 3'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:49:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '58fb8587-d62d-4bb4-b93d-13c1ab951596'	System	03 Sep 2020 03:49:56
User entered 'Yes (Y)'	System	03 Sep 2020 03:49:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '58fb8587-d62d-4bb4-b93d-13c1ab951596'	System	03 Sep 2020 03:49:56
User entered '98.7'	System	03 Sep 2020 03:49:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '58fb8587-d62d-4bb4-b93d-13c1ab951596'	System	03 Sep 2020 03:49:56
User entered 'No (N)'	System	03 Sep 2020 03:49:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '58fb8587-d62d-4bb4-b93d-13c1ab951596'	System	03 Sep 2020 03:49:56
User entered '02 Sep 2020 20:50'	System	03 Sep 2020 03:49:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 4'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '776d2b13-41d6-441b-97c2-dca1e38c8d43'	System	04 Sep 2020 03:32:22
User entered 'Yes (Y)'	System	04 Sep 2020 03:32:22

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:27', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '776d2b13-41d6-441b-97c2-dca1e38c8d43'	System	04 Sep 2020 03:32:22
User entered '98.6'	System	04 Sep 2020 03:32:22

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:31', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '776d2b13-41d6-441b-97c2-dca1e38c8d43'	System	04 Sep 2020 03:32:22
User entered 'No (N)'	System	04 Sep 2020 03:32:22

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:34', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '776d2b13-41d6-441b-97c2-dca1e38c8d43'	System	04 Sep 2020 03:32:22
User entered '03 Sep 2020 20:32'	System	04 Sep 2020 03:32:22

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 5'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:30:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '27e4ec61-e4d3-4d1f-9864-5294d75e0073'	System	05 Sep 2020 03:30:39
User entered 'Yes (Y)'	System	05 Sep 2020 03:30:39

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:30:43', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '27e4ec61-e4d3-4d1f-9864-5294d75e0073'	System	05 Sep 2020 03:30:39
User entered '97.8'	System	05 Sep 2020 03:30:39

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:30:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '27e4ec61-e4d3-4d1f-9864-5294d75e0073'	System	05 Sep 2020 03:30:39
User entered 'No (N)'	System	05 Sep 2020 03:30:39

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:30:49', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '27e4ec61-e4d3-4d1f-9864-5294d75e0073'	System	05 Sep 2020 03:30:39
User entered '04 Sep 2020 20:30'	System	05 Sep 2020 03:30:39

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 6'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:45:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0bb89a-c689-467f-9bb4-c4697066dd48'	System	06 Sep 2020 03:45:56
User entered 'Yes (Y)'	System	06 Sep 2020 03:45:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:01', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0bb89a-c689-467f-9bb4-c4697066dd48'	System	06 Sep 2020 03:45:56
User entered '97.9'	System	06 Sep 2020 03:45:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:05', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0bb89a-c689-467f-9bb4-c4697066dd48'	System	06 Sep 2020 03:45:56
User entered 'No (N)'	System	06 Sep 2020 03:45:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:08', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0bb89a-c689-467f-9bb4-c4697066dd48'	System	06 Sep 2020 03:45:56
User entered '05 Sep 2020 20:46'	System	06 Sep 2020 03:45:56

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 7'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:21', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f65f431-9150-447e-beb1-d728565a9d69'	System	07 Sep 2020 03:31:25
User entered 'Yes (Y)'	System	07 Sep 2020 03:31:25

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:31', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f65f431-9150-447e-beb1-d728565a9d69'	System	07 Sep 2020 03:31:25
User entered '98.2'	System	07 Sep 2020 03:31:25

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:35', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f65f431-9150-447e-beb1-d728565a9d69'	System	07 Sep 2020 03:31:25
User entered 'No (N)'	System	07 Sep 2020 03:31:25

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:37', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f65f431-9150-447e-beb1-d728565a9d69'	System	07 Sep 2020 03:31:25
User entered '06 Sep 2020 20:31'	System	07 Sep 2020 03:31:25

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:54:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '472f514b-ab80-4b23-854e-0681af4c79d3'	System	01 Sep 2020 01:54:41
User entered 'None (1)'	System	01 Sep 2020 01:54:41

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:54:28', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '472f514b-ab80-4b23-854e-0681af4c79d3'	System	01 Sep 2020 01:54:41
User entered 'No (N)'	System	01 Sep 2020 01:54:41

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:54:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '472f514b-ab80-4b23-854e-0681af4c79d3'	System	01 Sep 2020 01:54:41
User entered 'No (N)'	System	01 Sep 2020 01:54:41

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:54:48', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '472f514b-ab80-4b23-854e-0681af4c79d3'	System	01 Sep 2020 01:54:41
User entered 'None (1)'	System	01 Sep 2020 01:54:41

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:54:51', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '472f514b-ab80-4b23-854e-0681af4c79d3'	System	01 Sep 2020 01:54:41
User entered '31 Aug 2020 18:54'	System	01 Sep 2020 01:54:41

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 18:43'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 21:13'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:04:41', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '57d8b0d4-a58a-407d-8186-280a29aa8dde'	System	01 Sep 2020 17:06:27
User entered 'None (1)'	System	01 Sep 2020 17:06:27

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:04:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '57d8b0d4-a58a-407d-8186-280a29aa8dde'	System	01 Sep 2020 17:06:27
User entered 'Yes (Y)'	System	01 Sep 2020 17:06:27

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:06:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '57d8b0d4-a58a-407d-8186-280a29aa8dde'	System	01 Sep 2020 17:06:27
User entered '300'	System	01 Sep 2020 17:06:27

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:06:21', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '57d8b0d4-a58a-407d-8186-280a29aa8dde'	System	01 Sep 2020 17:06:27
User entered 'No (N)'	System	01 Sep 2020 17:06:27

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:06:32', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '57d8b0d4-a58a-407d-8186-280a29aa8dde'	System	01 Sep 2020 17:06:27
User entered 'None (1)'	System	01 Sep 2020 17:06:27

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:06:37', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '57d8b0d4-a58a-407d-8186-280a29aa8dde'	System	01 Sep 2020 17:06:27
User entered '01 Sep 2020 10:06'	System	01 Sep 2020 17:06:27

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 22:08'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 2'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '87fcd8b4-492a-42f5-9066-8ca121e3f030'	System	02 Sep 2020 01:22:52
User entered 'None (1)'	System	02 Sep 2020 01:22:52

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '87fcd8b4-492a-42f5-9066-8ca121e3f030'	System	02 Sep 2020 01:22:52
User entered 'No (N)'	System	02 Sep 2020 01:22:52

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:50', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '87fcd8b4-492a-42f5-9066-8ca121e3f030'	System	02 Sep 2020 01:22:52
User entered 'No (N)'	System	02 Sep 2020 01:22:52

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:22:57', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '87fcd8b4-492a-42f5-9066-8ca121e3f030'	System	02 Sep 2020 01:22:52
User entered 'None (1)'	System	02 Sep 2020 01:22:52

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:01', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '87fcd8b4-492a-42f5-9066-8ca121e3f030'	System	02 Sep 2020 01:22:52
User entered '01 Sep 2020 18:23'	System	02 Sep 2020 01:22:52

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 3'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:14', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '46620847-ce73-41a8-a40c-0dcfc9610801'	System	03 Sep 2020 03:50:36
User entered 'None (1)'	System	03 Sep 2020 03:50:36

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '46620847-ce73-41a8-a40c-0dcfc9610801'	System	03 Sep 2020 03:50:36
User entered 'No (N)'	System	03 Sep 2020 03:50:36

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:24', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '46620847-ce73-41a8-a40c-0dcfc9610801'	System	03 Sep 2020 03:50:36
User entered 'No (N)'	System	03 Sep 2020 03:50:36

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:44', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '46620847-ce73-41a8-a40c-0dcfc9610801'	System	03 Sep 2020 03:50:36
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 03:50:36

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '46620847-ce73-41a8-a40c-0dcfc9610801'	System	03 Sep 2020 03:50:36
User entered '02 Sep 2020 20:50'	System	03 Sep 2020 03:50:36

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 4'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:41', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '22632573-64a8-41a9-8e00-0767514a38e0'	System	04 Sep 2020 03:32:51
User entered 'None (1)'	System	04 Sep 2020 03:32:51

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:44', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '22632573-64a8-41a9-8e00-0767514a38e0'	System	04 Sep 2020 03:32:51
User entered 'No (N)'	System	04 Sep 2020 03:32:51

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:50', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '22632573-64a8-41a9-8e00-0767514a38e0'	System	04 Sep 2020 03:32:51
User entered 'No (N)'	System	04 Sep 2020 03:32:51

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '22632573-64a8-41a9-8e00-0767514a38e0'	System	04 Sep 2020 03:32:51
User entered 'None (1)'	System	04 Sep 2020 03:32:51

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:32:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '22632573-64a8-41a9-8e00-0767514a38e0' User entered '03 Sep 2020 20:32'	System	04 Sep 2020 03:32:51
	System	04 Sep 2020 03:32:51

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 5'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:30:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '16b82826-e6e0-40e4-b58f-f23e93cc3a86'	System	05 Sep 2020 03:30:57
User entered 'None (1)'	System	05 Sep 2020 03:30:57

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:30:58', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '16b82826-e6e0-40e4-b58f-f23e93cc3a86'	System	05 Sep 2020 03:30:57
User entered 'No (N)'	System	05 Sep 2020 03:30:57

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:02', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '16b82826-e6e0-40e4-b58f-f23e93cc3a86'	System	05 Sep 2020 03:30:57
User entered 'No (N)'	System	05 Sep 2020 03:30:57

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:06', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '16b82826-e6e0-40e4-b58f-f23e93cc3a86'	System	05 Sep 2020 03:30:57
User entered 'None (1)'	System	05 Sep 2020 03:30:57

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '16b82826-e6e0-40e4-b58f-f23e93cc3a86'	System	05 Sep 2020 03:30:57
User entered '04 Sep 2020 20:31'	System	05 Sep 2020 03:30:57

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 6'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:15', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fb4e0e61-35cd-4bca-b935-0d2ccd45571e'	System	06 Sep 2020 03:46:23
User entered 'None (1)'	System	06 Sep 2020 03:46:23

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fb4e0e61-35cd-4bca-b935-0d2ccd45571e'	System	06 Sep 2020 03:46:23
User entered 'No (N)'	System	06 Sep 2020 03:46:23

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:23', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fb4e0e61-35cd-4bca-b935-0d2ccd45571e'	System	06 Sep 2020 03:46:23
User entered 'No (N)'	System	06 Sep 2020 03:46:23

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:30', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fb4e0e61-35cd-4bca-b935-0d2ccd45571e'	System	06 Sep 2020 03:46:23
User entered 'None (1)'	System	06 Sep 2020 03:46:23

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fb4e0e61-35cd-4bca-b935-0d2ccd45571e'	System	06 Sep 2020 03:46:23
User entered '05 Sep 2020 20:46'	System	06 Sep 2020 03:46:23

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 7'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c59688e2-4144-4a86-859d-737e1cae4a0a'	System	07 Sep 2020 03:31:48
User entered 'None (1)'	System	07 Sep 2020 03:31:48

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c59688e2-4144-4a86-859d-737e1cae4a0a'	System	07 Sep 2020 03:31:48
User entered 'No (N)'	System	07 Sep 2020 03:31:48

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c59688e2-4144-4a86-859d-737e1cae4a0a'	System	07 Sep 2020 03:31:48
User entered 'No (N)'	System	07 Sep 2020 03:31:48

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:56', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c59688e2-4144-4a86-859d-737e1cae4a0a'	System	07 Sep 2020 03:31:48
User entered 'None (1)'	System	07 Sep 2020 03:31:48

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:31:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c59688e2-4144-4a86-859d-737e1cae4a0a'	System	07 Sep 2020 03:31:48
User entered '06 Sep 2020 20:31'	System	07 Sep 2020 03:31:48

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:02', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'None (0)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:05', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'None (0)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:14', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'None (0)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'None (0)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'None (0)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:36', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'None (0)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:55:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered 'No (N)'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-08-31T18:56:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'c4b6d67b-a58f-4a81-8bb6-dfa65a60ffd6'	System	01 Sep 2020 01:56:01
User entered '31 Aug 2020 18:56'	System	01 Sep 2020 01:56:01

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 18:43'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 21:13'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:06:43', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'None (0)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:06:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'None (0)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:07:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'None (0)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:07:13', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'None (0)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:07:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'None (0)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:07:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'None (0)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:07:30', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered 'No (N)'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T10:07:34', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a92359ef-477a-496e-8117-96091105a914'	System	01 Sep 2020 17:07:24
User entered '01 Sep 2020 10:07'	System	01 Sep 2020 17:07:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '31 Aug 2020 22:08'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 2'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'None (0)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:14', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'None (0)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'None (0)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'None (0)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'None (0)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:29', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'None (0)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:38', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered 'No (N)'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-01T18:23:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '26a81a4c-e38d-4d22-9948-ba7cbc8867e2'	System	02 Sep 2020 01:23:31
User entered '01 Sep 2020 18:23'	System	02 Sep 2020 01:23:31

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 3'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:53', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'None (0)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:56', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'None (0)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:50:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'None (0)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:51:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'None (0)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:51:06', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'None (0)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:51:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'None (0)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:51:17', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered 'No (N)'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-02T20:51:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '82f75e42-5ccf-4853-8ccb-ecaa1691220e'	System	03 Sep 2020 03:51:10
User entered '02 Sep 2020 20:51'	System	03 Sep 2020 03:51:10

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 4'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'None (0)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:06', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'None (0)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'None (0)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:12', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'None (0)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:15', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'None (0)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'None (0)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f'	System	04 Sep 2020 03:33:25
User entered 'No (N)'	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-03T20:33:35', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c502595-9ede-4fc2-b1df-da99052d198f' User entered '03 Sep 2020 20:33'	System	04 Sep 2020 03:33:25
	System	04 Sep 2020 03:33:25

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 5'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:13', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'None (0)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'None (0)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'None (0)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'None (0)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:25', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'None (0)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:28', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'None (0)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:31', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered 'No (N)'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-04T20:31:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '543b3529-5948-48ad-ac8f-e53a8a0ee15a'	System	05 Sep 2020 03:31:24
User entered '04 Sep 2020 20:31'	System	05 Sep 2020 03:31:24

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 6'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:40', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'None (0)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:44', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'None (0)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'None (0)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:49', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'None (0)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'None (0)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:46:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'None (0)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:47:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered 'No (N)'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-05T20:47:06', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '3a38d2a5-1b3a-4196-8bd1-a81c22170e38'	System	06 Sep 2020 03:46:56
User entered '05 Sep 2020 20:47'	System	06 Sep 2020 03:46:56

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 7'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'None (0)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'None (0)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:12', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'None (0)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:19', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'None (0)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:23', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'None (0)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'None (0)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered 'No (N)'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-06T20:32:58', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0601a41a-64b9-4de3-833e-e12c8f6c7500'	System	07 Sep 2020 03:32:46
User entered '06 Sep 2020 20:32'	System	07 Sep 2020 03:32:46

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 01:35:34

US3192614

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	10 Sep 2020 21:00:25

US3192614

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '10 Sep 2020' reason for change: Data Entry Error	Zoe Sesma (b) (4)	21 Sep 2020 21:04:38
User entered '09 Sep 2020'	maggie Tono (b) (4)	10 Sep 2020 21:00:25

US3192614

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
reason for change: Data Entry Error	Zoe Sesma (b) (4)	21 Sep 2020 21:04:23
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4)	
	maggie Tono (b) (4)	10 Sep 2020 21:00:25
	(b) (4)	

US3192614

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty; reason for change Data Entry Error	Zoe Sesma (b) (4)	21 Sep 2020 21:04:23
User entered 'left a voicemail to have the patient call back with the patient number'	maggie Tono (b) (4)	10 Sep 2020 21:00:25

US3192614

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	maggie Tono (b) (4)	10 Sep 2020 20:58:14

US3192614

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	10 Sep 2020 20:58:14

US3192614

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:05:02
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Sep 2020 21:04:54

US3192614

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:05:02
User entered '16 Sep 2020'	Zoe Sesma (b) (4)	21 Sep 2020 21:04:54

US3192614

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:05:02
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	21 Sep 2020 21:04:54

US3192614

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:05:02
User entered empty.	Zoe Sesma (b) (4)	21 Sep 2020 21:04:54

US3192614

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 04:05:02
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Sep 2020 21:04:59

US3192614

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	21 Sep 2020 21:04:59

US3192614

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Sep 2020 21:05:10

US3192614

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '21 Sep 2020'	Zoe Sesma (b) (4)	21 Sep 2020 21:05:10

US3192614

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	21 Sep 2020 21:05:10

US3192614

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Zoe Sesma (b) (4)	21 Sep 2020 21:05:10

US3192614

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	21 Sep 2020 21:05:15

US3192614

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	21 Sep 2020 21:05:15

US3192614

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:14

US3192614

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:14

US3192614

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:14

US3192614

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'VISIT2'	System	29 Sep 2020 23:38:14

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User accepted default value 'Pre-Dose (PREDOSE)'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51
	(b) (4)	

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '15:50'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered '29 Sep 2020 15:50'	System	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '98.4' F	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '72'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'bpm'	System	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '14'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'breaths/min'	System	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '166'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'mmHg'	System	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '81'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'mmHg'	System	29 Sep 2020 23:38:51

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User accepted default value 'Post-Dose (POSTDOSE)'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41
	(b) (4)	

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	(b) (4)	
	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41
	(b) (4)	

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '17:06'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered '29 Sep 2020 17:06'	System	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '98.1' F	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Oral (Oral)'	(b) (4)	
	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41
	(b) (4)	

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '66'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'bpm'	System	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '12'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'breaths/min'	System	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '154'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'mmHg'	System	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '86'	Saysamone Banks (b) (4)	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'mmHg'	System	30 Sep 2020 00:46:41

US3192614

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:59

US3192614

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	Zoe Sesma (b) (4)	29 Sep 2020 23:38:59

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Zoe Sesma (b) (4)	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Zoe Sesma (b) (4)	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'MRNA-1273 OR PLACEBO'	System	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '16:36'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered '29 Sep 2020 16:36'	System	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'ONCE'	System	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'INTRAMUSCULAR'	System	29 Sep 2020 23:39:11

US3192614

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:25

US3192614

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:25

US3192614

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '16:27'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:25

US3192614

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered '29 Sep 2020 16:27'	System	29 Sep 2020 23:39:25

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Sep 2020'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:45

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 23:39:45

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:45

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '16:29'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:45

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered '29 Sep 2020 16:29'	System	29 Sep 2020 23:39:45

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Zoe Sesma (b) (4) (b) (4)	29 Sep 2020 23:39:49

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'No (N)'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:49

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Zoe Sesma (b) (4)	29 Sep 2020 23:39:49

US3192614

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered empty.	System	29 Sep 2020 23:39:49

US3192614

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	29 Sep 2020 23:39:56

US3192614

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	29 Sep 2020 23:39:56

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:15', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a7fe2927-093d-4fe0-a461-6d67f7760bc9'	System	30 Sep 2020 00:05:24
User entered 'Yes (Y)'	System	30 Sep 2020 00:05:24

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a7fe2927-093d-4fe0-a461-6d67f7760bc9'	System	30 Sep 2020 00:05:24
User entered '98.1'	System	30 Sep 2020 00:05:24

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:32', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a7fe2927-093d-4fe0-a461-6d67f7760bc9'	System	30 Sep 2020 00:05:24
User entered 'No (N)'	System	30 Sep 2020 00:05:24

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:35', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a7fe2927-093d-4fe0-a461-6d67f7760bc9'	System	30 Sep 2020 00:05:24
User entered '29 Sep 2020 17:05'	System	30 Sep 2020 00:05:24

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 16:56'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 19:26'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:36:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'ff26ac2c-ffe7-4e5f-9013-c59aee58997d'	System	30 Sep 2020 03:36:57
User entered 'Yes (Y)'	System	30 Sep 2020 03:36:57

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'ff26ac2c-ffe7-4e5f-9013-c59aee58997d'	System	30 Sep 2020 03:36:57
User entered '98.6'	System	30 Sep 2020 03:36:57

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'ff26ac2c-ffe7-4e5f-9013-c59aee58997d'	System	30 Sep 2020 03:36:57
User entered 'No (N)'	System	30 Sep 2020 03:36:57

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'ff26ac2c-ffe7-4e5f-9013-c59aee58997d'	System	30 Sep 2020 03:36:57
User entered '29 Sep 2020 20:37'	System	30 Sep 2020 03:36:57

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 20:21'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 2'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:11:56', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0e9307-b896-485b-8861-ac0e595692aa'	System	01 Oct 2020 02:12:31
User entered 'Yes (Y)'	System	01 Oct 2020 02:12:31

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:12:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0e9307-b896-485b-8861-ac0e595692aa'	System	01 Oct 2020 02:12:31
User entered '98.1'	System	01 Oct 2020 02:12:31

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:12:40', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0e9307-b896-485b-8861-ac0e595692aa'	System	01 Oct 2020 02:12:31
User entered 'No (N)'	System	01 Oct 2020 02:12:31

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:12:43', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '9c0e9307-b896-485b-8861-ac0e595692aa'	System	01 Oct 2020 02:12:31
User entered '30 Sep 2020 19:12'	System	01 Oct 2020 02:12:31

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 3'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:39', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a6627cb5-3028-4f4c-966f-a1ab8b7ce5da'	System	02 Oct 2020 03:31:42
User entered 'Yes (Y)'	System	02 Oct 2020 03:31:42

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:48', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a6627cb5-3028-4f4c-966f-a1ab8b7ce5da'	System	02 Oct 2020 03:31:42
User entered '98.6'	System	02 Oct 2020 03:31:42

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:53', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a6627cb5-3028-4f4c-966f-a1ab8b7ce5da'	System	02 Oct 2020 03:31:42
User entered 'No (N)'	System	02 Oct 2020 03:31:42

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a6627cb5-3028-4f4c-966f-a1ab8b7ce5da'	System	02 Oct 2020 03:31:42
User entered '01 Oct 2020 20:31'	System	02 Oct 2020 03:31:42

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 4'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0c96dda1-682e-4fbf-85e1-94c854337a24'	System	03 Oct 2020 01:13:01
User entered 'Yes (Y)'	System	03 Oct 2020 01:13:01

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0c96dda1-682e-4fbf-85e1-94c854337a24'	System	03 Oct 2020 01:13:01
User entered '98.2'	System	03 Oct 2020 01:13:01

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:12', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0c96dda1-682e-4fbf-85e1-94c854337a24'	System	03 Oct 2020 01:13:01
User entered 'No (N)'	System	03 Oct 2020 01:13:01

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:15', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '0c96dda1-682e-4fbf-85e1-94c854337a24'	System	03 Oct 2020 01:13:01
User entered '02 Oct 2020 18:13'	System	03 Oct 2020 01:13:01

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 5'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:32:05', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a410d360-6c13-4f86-afc3-d382c9a84bc5'	System	04 Oct 2020 02:32:26
User entered 'Yes (Y)'	System	04 Oct 2020 02:32:26

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:32:12', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a410d360-6c13-4f86-afc3-d382c9a84bc5'	System	04 Oct 2020 02:32:26
User entered '98.4'	System	04 Oct 2020 02:32:26

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:32:17', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a410d360-6c13-4f86-afc3-d382c9a84bc5'	System	04 Oct 2020 02:32:26
User entered 'No (N)'	System	04 Oct 2020 02:32:26

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:32:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a410d360-6c13-4f86-afc3-d382c9a84bc5'	System	04 Oct 2020 02:32:26
User entered '03 Oct 2020 19:32'	System	04 Oct 2020 02:32:26

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 6'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:30:38', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8f3b7e5-8a56-4b0b-9f45-2524889d1f04'	System	05 Oct 2020 02:30:14
User entered 'Yes (Y)'	System	05 Oct 2020 02:30:14

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:30:45', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8f3b7e5-8a56-4b0b-9f45-2524889d1f04'	System	05 Oct 2020 02:30:14
User entered '98.6'	System	05 Oct 2020 02:30:14

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8f3b7e5-8a56-4b0b-9f45-2524889d1f04'	System	05 Oct 2020 02:30:14
User entered 'No (N)'	System	05 Oct 2020 02:30:14

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8f3b7e5-8a56-4b0b-9f45-2524889d1f04'	System	05 Oct 2020 02:30:14
User entered '04 Oct 2020 19:31'	System	05 Oct 2020 02:30:14

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 7'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:24', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b941f248-584a-4595-afef-26fd2dd264cc'	System	06 Oct 2020 04:35:49
User entered 'Yes (Y)'	System	06 Oct 2020 04:35:49

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:33', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b941f248-584a-4595-afef-26fd2dd264cc'	System	06 Oct 2020 04:35:49
User entered '98.2'	System	06 Oct 2020 04:35:49

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:40', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b941f248-584a-4595-afef-26fd2dd264cc'	System	06 Oct 2020 04:35:49
User entered 'No (N)'	System	06 Oct 2020 04:35:49

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b941f248-584a-4595-afef-26fd2dd264cc'	System	06 Oct 2020 04:35:49
User entered '05 Oct 2020 21:36'	System	06 Oct 2020 04:35:49

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a78efd88-d2f8-48e2-8c76-29461c0fa95d'	System	30 Sep 2020 00:05:52
User entered 'None (1)'	System	30 Sep 2020 00:05:52

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a78efd88-d2f8-48e2-8c76-29461c0fa95d'	System	30 Sep 2020 00:05:52
User entered 'No (N)'	System	30 Sep 2020 00:05:52

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:05:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a78efd88-d2f8-48e2-8c76-29461c0fa95d'	System	30 Sep 2020 00:05:52
User entered 'No (N)'	System	30 Sep 2020 00:05:52

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a78efd88-d2f8-48e2-8c76-29461c0fa95d'	System	30 Sep 2020 00:05:52
User entered 'None (1)'	System	30 Sep 2020 00:05:52

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'a78efd88-d2f8-48e2-8c76-29461c0fa95d'	System	30 Sep 2020 00:05:52
User entered '29 Sep 2020 17:06'	System	30 Sep 2020 00:05:52

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 16:56'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 19:26'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:21', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '71a2f23f-1417-48c8-8b8c-56a247fccdad'	System	30 Sep 2020 03:37:36
User entered 'None (1)'	System	30 Sep 2020 03:37:36

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:25', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '71a2f23f-1417-48c8-8b8c-56a247fccdad'	System	30 Sep 2020 03:37:36
User entered 'No (N)'	System	30 Sep 2020 03:37:36

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:30', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '71a2f23f-1417-48c8-8b8c-56a247fccdad'	System	30 Sep 2020 03:37:36
User entered 'No (N)'	System	30 Sep 2020 03:37:36

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:45', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '71a2f23f-1417-48c8-8b8c-56a247fccdad'	System	30 Sep 2020 03:37:36
User entered 'None (1)'	System	30 Sep 2020 03:37:36

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:48', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '71a2f23f-1417-48c8-8b8c-56a247fccdad'	System	30 Sep 2020 03:37:36
User entered '29 Sep 2020 20:37'	System	30 Sep 2020 03:37:36

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 20:21'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 2'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:12:49', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bf41461e-e570-4187-b76a-62695aa294d7'	System	01 Oct 2020 02:13:58
User entered 'None (1)'	System	01 Oct 2020 02:13:58

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:12:53', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bf41461e-e570-4187-b76a-62695aa294d7'	System	01 Oct 2020 02:13:58
User entered 'No (N)'	System	01 Oct 2020 02:13:58

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:12:58', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bf41461e-e570-4187-b76a-62695aa294d7'	System	01 Oct 2020 02:13:58
User entered 'No (N)'	System	01 Oct 2020 02:13:58

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bf41461e-e570-4187-b76a-62695aa294d7'	System	01 Oct 2020 02:13:58
User entered 'None (1)'	System	01 Oct 2020 02:13:58

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:11', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bf41461e-e570-4187-b76a-62695aa294d7'	System	01 Oct 2020 02:13:58
User entered '30 Sep 2020 19:14'	System	01 Oct 2020 02:13:58

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 3'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:19', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '6d0b3c69-a445-46a3-8488-c8a8035e9167'	System	02 Oct 2020 03:31:20
User entered 'None (1)'	System	02 Oct 2020 03:31:20

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:23', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '6d0b3c69-a445-46a3-8488-c8a8035e9167'	System	02 Oct 2020 03:31:20
User entered 'No (N)'	System	02 Oct 2020 03:31:20

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '6d0b3c69-a445-46a3-8488-c8a8035e9167'	System	02 Oct 2020 03:31:20
User entered 'No (N)'	System	02 Oct 2020 03:31:20

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:31', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '6d0b3c69-a445-46a3-8488-c8a8035e9167'	System	02 Oct 2020 03:31:20
User entered 'None (1)'	System	02 Oct 2020 03:31:20

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:34', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '6d0b3c69-a445-46a3-8488-c8a8035e9167'	System	02 Oct 2020 03:31:20
User entered '01 Oct 2020 20:31'	System	02 Oct 2020 03:31:20

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 4'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:14:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '23e766cf-8251-43ca-90f5-d3dde87e127c'	System	03 Oct 2020 01:14:04
User entered 'None (1)'	System	03 Oct 2020 01:14:04

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:14:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '23e766cf-8251-43ca-90f5-d3dde87e127c'	System	03 Oct 2020 01:14:04
User entered 'No (N)'	System	03 Oct 2020 01:14:04

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:14:12', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '23e766cf-8251-43ca-90f5-d3dde87e127c'	System	03 Oct 2020 01:14:04
User entered 'No (N)'	System	03 Oct 2020 01:14:04

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:14:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '23e766cf-8251-43ca-90f5-d3dde87e127c'	System	03 Oct 2020 01:14:04
User entered 'None (1)'	System	03 Oct 2020 01:14:04

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:14:19', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '23e766cf-8251-43ca-90f5-d3dde87e127c'	System	03 Oct 2020 01:14:04
User entered '02 Oct 2020 18:14'	System	03 Oct 2020 01:14:04

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 5'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:21', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '47d89b00-513e-4b47-bf3b-ff8520292e23'	System	04 Oct 2020 02:32:24
User entered 'None (1)'	System	04 Oct 2020 02:32:24

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '47d89b00-513e-4b47-bf3b-ff8520292e23'	System	04 Oct 2020 02:32:24
User entered 'No (N)'	System	04 Oct 2020 02:32:24

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:51', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '47d89b00-513e-4b47-bf3b-ff8520292e23'	System	04 Oct 2020 02:32:24
User entered 'No (N)'	System	04 Oct 2020 02:32:24

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:54', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '47d89b00-513e-4b47-bf3b-ff8520292e23'	System	04 Oct 2020 02:32:24
User entered 'None (1)'	System	04 Oct 2020 02:32:24

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:56', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '47d89b00-513e-4b47-bf3b-ff8520292e23'	System	04 Oct 2020 02:32:24
User entered '03 Oct 2020 19:31'	System	04 Oct 2020 02:32:24

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 6'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:39', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd4f23b57-05ec-453d-af8b-d906eb5fd8fb'	System	05 Oct 2020 02:31:02
User entered 'None (1)'	System	05 Oct 2020 02:31:02

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:45', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd4f23b57-05ec-453d-af8b-d906eb5fd8fb'	System	05 Oct 2020 02:31:02
User entered 'No (N)'	System	05 Oct 2020 02:31:02

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:49', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd4f23b57-05ec-453d-af8b-d906eb5fd8fb'	System	05 Oct 2020 02:31:02
User entered 'No (N)'	System	05 Oct 2020 02:31:02

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:53', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd4f23b57-05ec-453d-af8b-d906eb5fd8fb'	System	05 Oct 2020 02:31:02
User entered 'None (1)'	System	05 Oct 2020 02:31:02

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd4f23b57-05ec-453d-af8b-d906eb5fd8fb'	System	05 Oct 2020 02:31:02
User entered '04 Oct 2020 19:31'	System	05 Oct 2020 02:31:02

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 7'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '978736c9-754b-418c-99db-fa393098ef04'	System	06 Oct 2020 04:36:50
User entered 'None (1)'	System	06 Oct 2020 04:36:50

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:30', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '978736c9-754b-418c-99db-fa393098ef04'	System	06 Oct 2020 04:36:50
User entered 'No (N)'	System	06 Oct 2020 04:36:50

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:35', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '978736c9-754b-418c-99db-fa393098ef04'	System	06 Oct 2020 04:36:50
User entered 'No (N)'	System	06 Oct 2020 04:36:50

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:40', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '978736c9-754b-418c-99db-fa393098ef04'	System	06 Oct 2020 04:36:50
User entered 'None (1)'	System	06 Oct 2020 04:36:50

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '978736c9-754b-418c-99db-fa393098ef04'	System	06 Oct 2020 04:36:50
User entered '05 Oct 2020 21:37'	System	06 Oct 2020 04:36:50

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:11', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'None (0)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:13', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'None (0)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'None (0)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'None (0)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'None (0)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'None (0)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:30', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered 'No (N)'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T17:06:32', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'eabf3a89-53a2-409c-ac04-477cb5d238ba'	System	30 Sep 2020 00:06:19
User entered '29 Sep 2020 17:06'	System	30 Sep 2020 00:06:19

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 16:56'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 19:26'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 1, after vaccination (at home)'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'None (0)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:37:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'None (0)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:38:05', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'None (0)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:38:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'None (0)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:38:12', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'None (0)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:38:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'None (0)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:38:23', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered 'No (N)'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-29T20:38:25', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f8c33659-ca5a-4e9c-93ac-d9e11d6c422e'	System	30 Sep 2020 03:38:11
User entered '29 Sep 2020 20:38'	System	30 Sep 2020 03:38:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '29 Sep 2020 20:21'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '30 Sep 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 2'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:19', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'None (0)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:36', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'Significant; prevents daily activity (3)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:39', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'None (0)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:44', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'None (0)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'None (0)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:48', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'None (0)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:53', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered 'No (N)'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-09-30T19:14:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '2c8825a8-c490-4b39-87af-b8c887df8838'	System	01 Oct 2020 02:14:43
User entered '30 Sep 2020 19:14'	System	01 Oct 2020 02:14:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '30 Sep 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 3'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:30:42', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'None (0)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:30:47', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'No interference with activity (1)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:30:50', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'None (0)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:30:53', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'None (0)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:30:56', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'None (0)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:30:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'None (0)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:05', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered 'No (N)'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-01T20:31:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '4d67a9e4-dfad-4f35-9017-99998ff21030'	System	02 Oct 2020 03:30:55
User entered '01 Oct 2020 20:31'	System	02 Oct 2020 03:30:55

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '01 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 4'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:21', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'None (0)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'Some interference with activity (2)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:31', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'None (0)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:36', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'None (0)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:47', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:51', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'None (0)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:56', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered 'No (N)'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-02T18:13:59', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'e1578c28-e7ab-4c37-91dd-8af882144c2d'	System	03 Oct 2020 01:13:44
User entered '02 Oct 2020 18:13'	System	03 Oct 2020 01:13:44

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '02 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 5'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:30:48', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'None (0)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:30:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'None (0)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:30:54', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'None (0)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:30:57', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'None (0)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'None (0)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'None (0)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:11', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered 'No (N)'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-03T19:31:14', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'dbe2eecd-480d-4e20-8ae7-979e909b7162'	System	04 Oct 2020 02:31:01
User entered '03 Oct 2020 19:31'	System	04 Oct 2020 02:31:01

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '03 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 6'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:13', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'None (0)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:15', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'No interference with activity (1)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'None (0)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:20', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'None (0)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:23', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'None (0)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:26', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'None (0)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:31', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered 'No (N)'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-04T19:31:34', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd5675481-0287-4a0a-8eec-7207ea9db308'	System	05 Oct 2020 02:30:43
User entered '04 Oct 2020 19:31'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '04 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	29 Sep 2020 23:39:11
User entered 'Day 7'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:47', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'None (0)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:52', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'Some interference with activity (2)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:36:55', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'None (0)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'No interference with activity (1)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:06', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'None (0)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:08', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'None (0)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered 'No (N)'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-05T21:37:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '10965bab-de79-4aa1-9b34-3761040440ee'	System	06 Oct 2020 04:36:26
User entered '05 Oct 2020 21:37'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '05 Oct 2020 12:00'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Oct 2020 11:59'	System	29 Sep 2020 23:39:11

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	05 Oct 2020 02:30:43
User entered 'Day 8'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:45:33

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-06T21:27:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bc4f98cd-28db-4a07-a655-5a0347f3f209'	System	07 Oct 2020 04:26:21
User entered 'No interference with activity (1)'	System	07 Oct 2020 04:26:21

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-06T21:27:13', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'bc4f98cd-28db-4a07-a655-5a0347f3f209'	System	07 Oct 2020 04:26:21
User entered '06 Oct 2020 21:27'	System	07 Oct 2020 04:26:21

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	06 Oct 2020 04:36:26
User entered 'Day 9'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:45:33

Select one response below to indicate the intensity of your **FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-08T01:38:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b2467cad-52c0-4fb3-862b-ba5cf78e1232'	System	08 Oct 2020 08:37:13
User entered 'None (0)'	System	08 Oct 2020 08:37:13

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:45:33

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-08T01:38:03', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'b2467cad-52c0-4fb3-862b-ba5cf78e1232'	System	08 Oct 2020 08:37:13
User entered '08 Oct 2020 01:38'	System	08 Oct 2020 08:37:13

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: Fatigue_Day(9)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	06 Oct 2020 04:36:26
User entered 'Day 8'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:45:33

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-06T21:27:19', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '69a6f5f8-0360-4088-b873-1cdeccf76452'	System	07 Oct 2020 04:26:29
User entered 'None (0)'	System	07 Oct 2020 04:26:29

US3192614

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-06T21:27:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '69a6f5f8-0360-4088-b873-1cdeccf76452'	System	07 Oct 2020 04:26:29
User entered '06 Oct 2020 21:27'	System	07 Oct 2020 04:26:29

US3192614

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Oct 2020 12:00'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 04:36:26

US3192614

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
Data entry locked.	System	05 Oct 2020 02:30:43
User entered 'Day 8'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:45:33

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 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-06T21:27:29', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '14d5131d-8333-44f3-98a2-cb61712cdba5'	System	07 Oct 2020 04:26:39
User entered 'No (N)'	System	07 Oct 2020 04:26:39

US3192614

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-10-06T21:27:32', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '14d5131d-8333-44f3-98a2-cb61712cdba5'	System	07 Oct 2020 04:26:39
User entered '06 Oct 2020 21:27'	System	07 Oct 2020 04:26:39

US3192614

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '06 Oct 2020 12:00'	System	05 Oct 2020 02:30:43

US3192614

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 15:45:33

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 19:26:53
User entered '07 Oct 2020 11:59'	System	05 Oct 2020 02:30:43

US3192614

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:56

US3192614

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '9 Oct 2020'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:56

US3192614

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:56

US3192614

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:13:56

US3192614

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	12 Oct 2020 16:14:01

US3192614

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	12 Oct 2020 16:14:01

US3192614

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 01:02:49

US3192614

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 01:02:49

US3192614

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 01:02:49

US3192614

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Oct 2020 01:02:49

US3192614

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Oct 2020 01:02:53

US3192614

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	14 Oct 2020 01:02:53

US3192614

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:33:52

US3192614

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:33:52

US3192614

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:33:52

US3192614

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:33:52

US3192614

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 22:33:58

US3192614

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	23 Oct 2020 22:33:58

US3192614

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	30 Oct 2020 00:19:34

US3192614

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Oct 2020'	Zoe Sesma (b) (4)	30 Oct 2020 00:19:34

US3192614

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	30 Oct 2020 00:19:34

US3192614

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'VISIT3'	System	30 Oct 2020 00:19:34

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Oct 2020'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '15:58'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered '29 Oct 2020 15:58'	System	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '98.2' F	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered empty.	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '86'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'bpm'	System	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '14'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'breaths/min'	System	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '162'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'mmHg'	System	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '82'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'mmHg'	System	30 Oct 2020 00:20:12

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41

US3192614

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41

US3192614

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:21

US3192614

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Oct 2020'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:21

US3192614

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:36

US3192614

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '29 Oct 2020'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:36

US3192614

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered '16:16'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:36

US3192614

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered '29 Oct 2020 16:16'	System	30 Oct 2020 00:20:36

US3192614

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User signature succeeded.	John McGettigan (b) (4)	14 Feb 2021 03:14:55
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	30 Oct 2020 00:20:41

US3192614

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:41
User entered 'I'	System	30 Oct 2020 00:20:41

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 64'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Please 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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
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US3192614

Folder: Safety Follow Up Diary (1)

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[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)	24 Apr 2021 13:57:20
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered '31 Oct 2020 00:01'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered '04 Nov 2020 23:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 71'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

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US3192614

Folder: Safety Follow Up Diary (1)

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[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
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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.](#)

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[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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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US3192614

Folder: Safety Follow Up Diary (1)

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: 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.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
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[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)
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[Date and time of submission](#)

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[Patient Cloud Open Date & Time](#)

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DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered '07 Nov 2020 00:01'	System	01 Sep 2020 01:35:34

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[Patient Cloud Close Date & Time](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered '11 Nov 2020 23:59'	System	01 Sep 2020 01:35:34

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TIMEPOINT

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered 'Day 78'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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)
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[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Please 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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Please 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)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered '14 Nov 2020 00:01'	System	01 Sep 2020 01:35:34

US3192614

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:26:11
Data entry locked.	System	01 Sep 2020 01:35:34
User entered '18 Nov 2020 23:59'	System	01 Sep 2020 01:35:34

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2020-12-24T13:36:18', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '049a270e-664a-45d8-b5ee-53c4a69bdf7'	System	24 Dec 2020 20:35:04
User entered 'Yes (Y)'	System	24 Dec 2020 20:35:04

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2020-12-24T13:36:30', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '049a270e-664a-45d8-b5ee-53c4a69bdf7'	System	24 Dec 2020 20:35:04
User entered 'No (N)'	System	24 Dec 2020 20:35:04

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-12-24T13:36:38', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '049a270e-664a-45d8-b5ee-53c4a69bdf7'	System	24 Dec 2020 20:35:04
User entered 'No (N)'	System	24 Dec 2020 20:35:04

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-12-24T13:37:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '049a270e-664a-45d8-b5ee-53c4a69bdf7'	System	24 Dec 2020 20:35:04
User entered 'No (N)'	System	24 Dec 2020 20:35:04

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2020-12-24T13:37:09', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '049a270e-664a-45d8-b5ee-53c4a69bdf7'	System	24 Dec 2020 20:35:04
User entered '24 Dec 2020 13:37:09'	System	24 Dec 2020 20:35:04

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-01-01T12:00:39', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f07ecc75-6e1a-43cd-a418-94f483e4534a'	System	01 Jan 2021 18:58:41
User entered 'No (N)'	System	01 Jan 2021 18:58:41

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-01-01T12:00:44', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f07ecc75-6e1a-43cd-a418-94f483e4534a'	System	01 Jan 2021 18:58:41
User entered 'No (N)'	System	01 Jan 2021 18:58:41

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-01-01T12:00:48', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'f07ecc75-6e1a-43cd-a418-94f483e4534a' User entered '01 Jan 2021 12:00:48'	System	01 Jan 2021 18:58:41

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-01-08T20:45:08', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '80bd75ad-6599-4a95-8fae-bb2f271dfca6'	System	09 Jan 2021 03:43:10
User entered 'No (N)'	System	09 Jan 2021 03:43:10

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-01-08T20:45:14', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '80bd75ad-6599-4a95-8fae-bb2f271dfca6'	System	09 Jan 2021 03:43:10
User entered 'No (N)'	System	09 Jan 2021 03:43:10

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-01-08T20:45:17', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '80bd75ad-6599-4a95-8fae-bb2f271dfca6'	System	09 Jan 2021 03:43:10
User entered '08 Jan 2021 20:45:17'	System	09 Jan 2021 03:43:10

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-01-14T07:43:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '945b3218-8c30-43d4-bdbb-fe7ec1d5cc7d'	System	14 Jan 2021 14:41:28
User entered 'No (N)'	System	14 Jan 2021 14:41:28

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-01-14T07:43:32', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '945b3218-8c30-43d4-bdbb-fe7ec1d5cc7d'	System	14 Jan 2021 14:41:28
User entered 'No (N)'	System	14 Jan 2021 14:41:28

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-01-14T07:43:36', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '945b3218-8c30-43d4-bdbb-fe7ec1d5cc7d' User entered '14 Jan 2021 07:43:36'	System	14 Jan 2021 14:41:28
	System	14 Jan 2021 14:41:28

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-01-20T09:13:46', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd6a9f30b-3c12-43e0-a9d4-8b6686a09ec2'	System	20 Jan 2021 16:12:16
User entered 'No (N)'	System	20 Jan 2021 16:12:16

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-01-20T09:14:22', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd6a9f30b-3c12-43e0-a9d4-8b6686a09ec2'	System	20 Jan 2021 16:12:16
User entered 'No (N)'	System	20 Jan 2021 16:12:16

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-01-20T09:14:25', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'd6a9f30b-3c12-43e0-a9d4-8b6686a09ec2'	System	20 Jan 2021 16:12:16
User entered '20 Jan 2021 09:14:25'	System	20 Jan 2021 16:12:16

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-02-11T16:32:58', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '39eefaf4-6b35-4c19-b64a-bbab985d75ef'	System	11 Feb 2021 23:30:26
User entered 'No (N)'	System	11 Feb 2021 23:30:26

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-02-11T16:33:07', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '39eefaf4-6b35-4c19-b64a-bbab985d75ef'	System	11 Feb 2021 23:30:26
User entered 'No (N)'	System	11 Feb 2021 23:30:26

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-02-11T16:33:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '39eefaf4-6b35-4c19-b64a-bbab985d75ef'	System	11 Feb 2021 23:30:26
User entered '11 Feb 2021 16:33:10'	System	11 Feb 2021 23:30:26

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-02-19T14:13:10', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'cc692b32-1b5a-483c-aebc-41b965d6c742'	System	19 Feb 2021 21:10:34
User entered 'No (N)'	System	19 Feb 2021 21:10:34

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-02-19T14:13:16', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'cc692b32-1b5a-483c-aebc-41b965d6c742'	System	19 Feb 2021 21:10:34
User entered 'No (N)'	System	19 Feb 2021 21:10:34

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-02-19T14:13:19', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'cc692b32-1b5a-483c-aebc-41b965d6c742'	System	19 Feb 2021 21:10:34
User entered '19 Feb 2021 14:13:19'	System	19 Feb 2021 21:10:34

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-02-24T13:17:57', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '417a5437-3a93-4e08-a291-ce1e297e9df3'	System	24 Feb 2021 20:18:41
User entered 'No (N)'	System	24 Feb 2021 20:18:41

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-02-24T13:18:01', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '417a5437-3a93-4e08-a291-ce1e297e9df3'	System	24 Feb 2021 20:18:41
User entered 'No (N)'	System	24 Feb 2021 20:18:41

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-02-24T13:18:04', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '417a5437-3a93-4e08-a291-ce1e297e9df3' User entered '24 Feb 2021 13:18:04'	System	24 Feb 2021 20:18:41

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-03-11T15:12:26-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '7fa4ab85-04c7-4895-9114-d0a77499bfb6'	System	11 Mar 2021 22:09:50
User entered 'No (N)'	System	11 Mar 2021 22:09:50

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-03-11T15:12:33-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '7fa4ab85-04c7-4895-9114-d0a77499bfb6'	System	11 Mar 2021 22:09:50
User entered 'No (N)'	System	11 Mar 2021 22:09:50

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-03-11T15:12:35-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '7fa4ab85-04c7-4895-9114-d0a77499bfb6' User entered '11 Mar 2021 15:12:35'	System	11 Mar 2021 22:09:50
	System	11 Mar 2021 22:09:50

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-03-19T17:14:53-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f9fc9b7-57a5-43b6-925c-7b1fd9cb3c9a'	System	20 Mar 2021 00:11:49
User entered 'No (N)'	System	20 Mar 2021 00:11:49

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-03-19T17:14:57-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f9fc9b7-57a5-43b6-925c-7b1fd9cb3c9a'	System	20 Mar 2021 00:11:49
User entered 'No (N)'	System	20 Mar 2021 00:11:49

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-03-19T17:14:59-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '8f9fc9b7-57a5-43b6-925c-7b1fd9cb3c9a'	System	20 Mar 2021 00:11:49
User entered '19 Mar 2021 17:14:59'	System	20 Mar 2021 00:11:49

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[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 (0b68e15b84978e93)', Time: '2021-04-11T16:43:56-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fddad01e-746b-4156-bfa0-d88a6548a4e8'	System	11 Apr 2021 23:40:26
User entered 'No (N)'	System	11 Apr 2021 23:40:26

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

Have you been exposed to someone with 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 (0b68e15b84978e93)', Time: '2021-04-11T16:43:59-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fddad01e-746b-4156-bfa0-d88a6548a4e8'	System	11 Apr 2021 23:40:26
User entered 'No (N)'	System	11 Apr 2021 23:40:26

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-04-11T16:44:02-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: 'fddad01e-746b-4156-bfa0-d88a6548a4e8'	System	11 Apr 2021 23:40:26
User entered '11 Apr 2021 16:44:02'	System	11 Apr 2021 23:40:26

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:26:11

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:26:11

US3192614

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:45:33

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:26:11
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:26:11

US3192614

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:45:33

[Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-03-11T15:12:13-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '640b37db-4c78-4efb-a170-efb044740c3d'	System	11 Mar 2021 22:09:30
User entered 'No (N)'	System	11 Mar 2021 22:09:30

US3192614

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:45:33

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 13:57:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (0b68e15b84978e93)', Time: '2021-03-11T15:12:17-07:00', User OID: 'PatientReportedOutcome (US3192614)', ODM File OID: '640b37db-4c78-4efb-a170-efb044740c3d' User entered '11 Mar 2021 15:12:17'	System	11 Mar 2021 22:09:30
	System	11 Mar 2021 22:09:30

US3192614

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:30:13
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	01 Dec 2020 15:47:01

US3192614

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:30:13
User entered '27 Nov 2020'	Amanda Hermosillo (b) (4)	01 Dec 2020 15:47:01

US3192614

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:30:13
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amanda Hermosillo (b) (4)	01 Dec 2020 15:47:01

US3192614

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:30:13
User entered empty.	Amanda Hermosillo (b) (4)	01 Dec 2020 15:47:01

US3192614

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User signature succeeded.	John McGettigan (b) (4)	09 Mar 2021 17:30:13
User entered 'Yes (Y)'	Amanda Hermosillo (b) (4)	01 Dec 2020 15:47:05

US3192614

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 23:48:08
User entered 'I'	System	01 Dec 2020 15:47:05

US3192614

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 23:01:49

US3192614

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '31 Dec 2020'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 23:01:49

US3192614

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 23:01:49

US3192614

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Jan 2021 23:01:49

US3192614

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Jan 2021 23:01:54

US3192614

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User entered 'I'	System	09 Jan 2021 23:01:54

US3192614

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:09

US3192614

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:09

US3192614

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:09

US3192614

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:09

US3192614

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:13

US3192614

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User entered 'I'	System	04 Mar 2021 23:48:13

US3192614

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:30

US3192614

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:30

US3192614

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:30

US3192614

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:30

US3192614

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:48:33

US3192614

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 23:06:24
User entered 'I'	System	04 Mar 2021 23:48:33

US3192614

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	08 Apr 2021 22:23:30

US3192614

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '8 Apr 2021'	Zoe Sesma (b) (4)	08 Apr 2021 22:23:30

US3192614

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	08 Apr 2021 22:23:30

US3192614

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'VISIT4'	System	08 Apr 2021 22:23:30

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '8 Apr 2021'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '15:04'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '8 Apr 2021 15:04'	System	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '97.5' F	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered empty.	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '88'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'bpm'	System	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '16'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'breaths/min'	System	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '178'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'mmHg'	System	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '85'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered 'mmHg'	System	08 Apr 2021 22:24:28

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57

US3192614

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57

US3192614

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'No (N)'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:34

US3192614

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered empty.	Zoe Sesma (b) (4)	08 Apr 2021 22:24:34

US3192614

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:49

US3192614

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '8 Apr 2021'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:49

US3192614

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered '15:13'	Zoe Sesma (b) (4)	08 Apr 2021 22:24:49

US3192614

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '8 Apr 2021 15:13'	System	08 Apr 2021 22:24:49

US3192614

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User signature succeeded.	John McGettigan (b) (4)	12 Apr 2021 18:00:02
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	08 Apr 2021 22:25:57

US3192614

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:15:57
User entered '1'	System	08 Apr 2021 22:25:57

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:11:49

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:11:49

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	14 Jan 2021 23:11:49

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 23:11:49

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:26:04

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 14:26:04

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:34:32
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4) (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 13:34:32
User entered 'Placebo (Placebo)'	Zoe Sesma (b) (4) (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '1'	System	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 15:45:33

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'I'	System	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '69' in	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '226.2' lb	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '33.47375'	System	14 Jan 2021 23:13:26
DataPoint set to visible.	System	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '69' in	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '226.2' lb	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '33.47375'	System	14 Jan 2021 23:13:26
DataPoint set to visible.	System	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User accepted default value 'Pre-Dose (PREDOSE)'	Zoe Sesma (b) (4) (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '15:14'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '14 Jan 2021 15:14'	System	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '98.4' F	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '77'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'bpm'	System	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'breaths/min'	System	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '165'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '83'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '69' in	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '226.2' lb	Zoe Sesma (b) (4)	14 Jan 2021 23:13:26

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:45:33

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '33.47375'	System	14 Jan 2021 23:13:26
DataPoint set to visible.	System	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User accepted default value 'Post-Dose (POSTDOSE)'	Zoe Sesma (b) (4) (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '16:32'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '14 Jan 2021 16:32'	System	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '99.0' F	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '68'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'bpm'	System	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '12'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'breaths/min'	System	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '158'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '82'	Zoe Sesma (b) (4)	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	14 Jan 2021 23:55:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:35

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:35

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mRNA-1273'	System	14 Jan 2021 23:13:47
DataPoint set to visible.	System	14 Jan 2021 23:12:24

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '16:02'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '14 Jan 2021 16:02'	System	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'ONCE'	System	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'INTRAMUSCULAR'	System	14 Jan 2021 23:13:47

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:01

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:01

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '15:27'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:01

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '14 Jan 2021 15:27'	System	14 Jan 2021 23:14:01

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:08

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14 Jan 2021'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:08

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '15:28'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:08

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:45:33

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '14 Jan 2021 15:28'	System	14 Jan 2021 23:14:08

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	14 Jan 2021 23:14:12

US3192614

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'I'	System	14 Jan 2021 23:14:12

US3192614

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 22:16:40

US3192614

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 22:16:40

US3192614

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 22:16:40

US3192614

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Jan 2021 22:16:40

US3192614

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Jan 2021 22:16:46

US3192614

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'I'	System	31 Jan 2021 22:16:46

US3192614

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '1'	System	31 Jan 2021 22:16:46
DataPoint set to visible.	System	31 Jan 2021 22:16:46

US3192614

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Feb 2021 00:25:43

US3192614

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Feb 2021'	Zoe Sesma (b) (4)	12 Feb 2021 00:25:43

US3192614

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	12 Feb 2021 00:25:43

US3192614

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'OLD29'	System	12 Feb 2021 00:25:43

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User accepted default value 'Pre-Dose (PREDOSE)'	Zoe Sesma (b) (4) (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Feb 2021'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '15:50'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '11 Feb 2021 15:50'	System	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '98.2' F	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '67'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'bpm'	System	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '12'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'breaths/min'	System	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '157'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '84'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	12 Feb 2021 00:26:16

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User accepted default value 'Post-Dose (POSTDOSE)'	Zoe Sesma (b) (4) (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Feb 2021'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '16:35'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '11 Feb 2021 16:35'	System	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '98.5' F	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '68'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'bpm'	System	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '12'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'breaths/min'	System	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '166'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '89'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	12 Feb 2021 00:26:37

US3192614

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:42

US3192614

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Feb 2021'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:42

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mRNA-1273'	System	12 Feb 2021 00:26:50
DataPoint set to visible.	System	31 Jan 2021 22:16:46

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Feb 2021'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '16:05'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '11 Feb 2021 16:05'	System	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Left Arm (LEFT ARM)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'ONCE'	System	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:45:33

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 00:26:50

US3192614

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Feb 2021 00:26:55

US3192614

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '1'	System	12 Feb 2021 00:26:55

US3192614

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:05

US3192614

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '19 Feb 2021'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:05

US3192614

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Contact Made (CONTACT MADE)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:05

US3192614

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:45:33

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	12 Mar 2021 00:16:05

US3192614

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:15

US3192614

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:45:33

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'I'	System	12 Mar 2021 00:16:15

US3192614

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:25

US3192614

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Mar 2021'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:25

US3192614

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Clinic (Clinic)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:25

US3192614

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:45:33

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'OLD57'	System	12 Mar 2021 00:16:25

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Mar 2021'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '16:18'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '11 Mar 2021 16:18'	System	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '98.8' F	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (Oral)'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '63'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'bpm'	System	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '14'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'breaths/min'	System	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '171'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '86'	Zoe Sesma (b) (4)	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered 'mmHg'	System	12 Mar 2021 00:16:52

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36

US3192614

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:45:33

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36

US3192614

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Mar 2021 00:18:15

US3192614

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:45:33

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Mar 2021'	Zoe Sesma (b) (4)	12 Mar 2021 00:18:15

US3192614

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	Zoe Sesma (b) (4)	12 Mar 2021 00:18:25

US3192614

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '11 Mar 2021'	Zoe Sesma (b) (4)	12 Mar 2021 00:18:25

US3192614

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '16:28'	Zoe Sesma (b) (4)	12 Mar 2021 00:18:25

US3192614

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:45:33

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:58:36
User entered '11 Mar 2021 16:28'	System	12 Mar 2021 00:18:25

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Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:45:33

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:29:37
User signature succeeded.	John McGettigan (b) (4)	28 Mar 2021 18:40:41
User closed query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Mar 2021 10:29:09
Query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'updated' (Site from DM).	maggie Tono (b) (4) (b) (4)	19 Mar 2021 18:45:49
User opened query 'Per DM CLR: Please note, Per Diary Dose 2 Record, symptom of FATIGUE persist beyond Day 7 (start date: Day 2; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 07:59:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 22:32:28
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:11:10

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4)	31 Oct 2020 00:52:04
Reviewed for Safety.	(b) (4), (b) (6)	17 Sep 2020 15:52:10
User entered	System	17 Sep 2020 15:51:58
'USA-US097-2020-mRNA-1273-P301000002'		
User entered 'New'	(b) (4), (b) (6)	17 Sep 2020 15:51:58

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Pericardial disorders NEC, PT: Pericardial effusion, LLT: Pericardial effusion - version MedDRA\\23.0.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 11:06:12
Data point term sent to Coder	(b) (4)	
DataPoint Un-verified.	Coder Import (b) (4)	08 Apr 2021 11:06:12
	(b) (4)	
	System	08 Apr 2021 02:52:41
	Damaris Atondo (b) (4)	08 Apr 2021 02:51:42
	(b) (4)	
Coding entries removed.	Damaris Atondo (b) (4)	08 Apr 2021 02:51:42
	(b) (4)	
User entered 'PERICARDITIS effusion' reason for change: Data Entry Error	Damaris Atondo (b) (4)	08 Apr 2021 02:51:42
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Nov 2020 19:14:30
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).		23 Nov 2020 14:28:57
User coded data point as SOC: Cardiac disorders, HLGT: Pericardial disorders, HLT: Noninfectious pericarditis, PT: Pericarditis, LLT: Pericarditis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 23:52:05
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 23:52:05
Data point term sent to Coder	(b) (4)	
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'updated ' (Site from Safety).	System	20 Nov 2020 23:51:48
DataPoint Un-verified.	Yvonne De Los Reyes	20 Nov 2020 23:51:41
	(b) (4)	
	Yvonne De Los Reyes	20 Nov 2020 23:51:36
	(b) (4)	
Coding entries removed.	Yvonne De Los Reyes	20 Nov 2020 23:51:36
	(b) (4)	
User entered 'Pericarditis' reason for change: Data Entry Error	Yvonne De Los Reyes	20 Nov 2020 23:51:36
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:32:21
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Angina pectoris, LLT: Chest pain - cardiac - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:25:36
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 21:25:36
Data point term sent to Coder	(b) (4)	12 Nov 2020 21:24:58
User closed query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).'	System	12 Nov 2020 21:24:18
(Site from System).		
Query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).'	Amanda Hermosillo	12 Nov 2020 21:24:18
answered with 'Updated' (Site from System).	(b) (4)	
DataPoint Un-verified.	Amanda Hermosillo	12 Nov 2020 21:24:12
	(b) (4)	
Coding entries removed.	Amanda Hermosillo	12 Nov 2020 21:24:12
	(b) (4)	
User entered 'Cardiac CHEST PAIN' reason for change: Data Entry Error	Amanda Hermosillo	12 Nov 2020 21:24:12
	(b) (4)	
User opened query 'For coding purposes, for the term CHEST PAIN please specify if this is CARDIAC CHEST PAIN, MUSCULOSKELETAL CHEST PAIN or specify the etiology of the chest pain (ex.- pleural pain, heartburn related chest pain, cancer pain,unknown etiology,etc).'	Coder Import (b) (4)	10 Nov 2020 20:02:39
(Site from System).	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.'	(b) (4), (b) (6)	09 Nov 2020 18:40:17
(Site from Safety).		
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.'		02 Nov 2020 22:37:49
(Site from Safety).		
DataPoint Verified.		31 Oct 2020 00:52:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	31 Oct 2020 00:36:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	31 Oct 2020 00:36:15
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	31 Oct 2020 00:35:24
Query 'PV Query: Please consider updating the event	Yvonne De Los Reyes	31 Oct 2020 00:35:11
term to the underlying cause/etiology of the event.'	(b) (4)	
answered with 'amended' (Site from Safety).		
Coding entries removed.	Yvonne De Los Reyes	31 Oct 2020 00:34:55
	(b) (4)	
User entered 'Chest pain' reason for change: Data	Yvonne De Los Reyes	31 Oct 2020 00:34:55
Entry Error	(b) (4)	
User opened query 'PV Query: Please consider	(b) (4), (b) (6)	15 Oct 2020 15:19:38
updating the event term to the underlying		
cause/etiology of the event.' (Site from Safety).		
Query 'PV Query: Please consider updating the event		07 Oct 2020 14:44:59
term to the underlying cause/etiology of the event.'		
canceled (Site from Safety).		
User opened query 'PV Query: Please consider		02 Oct 2020 14:35:31
updating the event term to the underlying		
cause/etiology of the event.' (Site from Safety).		
User coded data point as SOC: Respiratory, thoracic	Coder Import (b) (4)	16 Sep 2020 23:13:48
and mediastinal disorders, HLG: Respiratory	(b) (4)	
disorders NEC, HLT: Breathing abnormalities, PT:		
Dyspnoea, LLT: Shortness of breath - version		
MedDRA\\23.0.		
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Sep 2020 23:13:48
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	16 Sep 2020 23:13:08
User entered 'Shortness of breath'	Yvonne De Los Reyes	16 Sep 2020 23:12:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:52:51
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:52:57
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:04
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:06
User entered '11 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
User entered '10 Sep 2020'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:30:17
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 23:18:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 23:18:56
User entered empty; reason for change Data Entry Error	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:18:56
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	16 Sep 2020 23:12:40
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	16 Sep 2020 23:12:40
User entered 'un:un' (non-conformant).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 23:18:56
User entered '10 Sep 2020 UN:UN' (non-conformant).	System	16 Sep 2020 23:12:40

US3192614

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:11
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:38:06
		31 Oct 2020 00:54:07
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:35:17
User entered '15 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:17:42
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).		07 Oct 2020 14:45:22
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		02 Oct 2020 14:33:10
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:19
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Sep 2020 23:12:40

US3192614

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4)	
Query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 15:14:29
DataPoint Un-verified.	Yvonne De Los Reyes (b) (4)	13 Mar 2021 17:16:38
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	13 Mar 2021 17:16:05
User opened query 'PV Query: As the subject was admitted to the hospital please consider updating the severity of the event to Grade 4.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:25:44
DataPoint Verified.		31 Oct 2020 00:54:22
Query 'PV Query: Please provide event severity.' canceled (Site from Safety).		07 Oct 2020 14:45:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	maggie Tono (b) (4)	06 Oct 2020 23:43:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	06 Oct 2020 02:07:14
User opened query 'PV Query: Please provide event severity.' (Site from Safety).		02 Oct 2020 14:32:34
Query 'Data is required. Please complete.' answered with 'unknown at this time ' (Site from System).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:17:33
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:12:40
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:23
User entered 'Yes (Y)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

US3192614

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:25
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:27
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Requires inpatient or prolongation of existing Hospitalization

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:46:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'discharge summary sent via email' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:04:23
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 21:07:15
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:29
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).		06 Oct 2020 02:08:35
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 'unknown at this time ' (Site from System).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:19:05
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	16 Sep 2020 23:12:40
User entered '1'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:32
User entered '14 Sep 2020'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:38:18
DataPoint Verified.		31 Oct 2020 00:54:33
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:35:25
User entered '15 Sep 2020' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:18:51
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).		07 Oct 2020 14:45:29
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		02 Oct 2020 14:33:56
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4) (d) (4), (b) (6)	02 Nov 2020 22:38:26
DataPoint Verified.		31 Oct 2020 00:54:38
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'confirmed ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:35:31
User entered 'No (N)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:21
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' canceled (Site from Safety).		07 Oct 2020 14:45:31
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).		06 Oct 2020 02:08:48
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).		02 Oct 2020 14:34:47
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'unknown at this time ' (Site from System).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:19:09
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	16 Sep 2020 23:12:40
User entered 'Unknown (UNK)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:41
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:42
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:44
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:54:45
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	31 Oct 2020 00:54:47
User closed query 'Data is required. Please complete.' (Site from System).		06 Oct 2020 02:09:02
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		24 Sep 2020 13:59:56
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'updated ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	23 Sep 2020 18:52:34
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	23 Sep 2020 18:51:44
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:46:46
Query 'Data is required. Please complete.' answered with 'unknown at this time ' (Site from System).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:18:37
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:12:40
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 22:30:43
User closed query 'Relationship to study procedure is not documented. Please reconcile. Thanks' (Site from CRA).		12 Nov 2020 22:30:41
Query 'Relationship to study procedure is not documented. Please reconcile. Thanks' answered with 'updated' (Site from CRA).	Amanda Hermosillo (b) (4)	12 Nov 2020 21:23:12
User opened query 'Relationship to study procedure is not documented. Please reconcile. Thanks' (Site from CRA).	(b) (4), (b) (6)	31 Oct 2020 00:56:05
User closed query 'Per CDM: Response noted. However the "Relationship to study procedure" is missing. Please update the data else clarify. Thank you.' (Site from DM).		11 Oct 2020 21:23:01
Query 'Per CDM: Response noted. However the "Relationship to study procedure" is missing. Please update the data else clarify. Thank you.' answered with 'have updated this query ' (Site from DM).	maggie Tono (b) (4)	09 Oct 2020 20:36:18
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	maggie Tono (b) (4)	09 Oct 2020 20:35:52
User opened query 'Per CDM: Response noted. However the "Relationship to study procedure" is missing. Please update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 02:12:07
User closed query 'Data is required. Please complete.' (Site from System).		06 Oct 2020 02:09:22
Query 'Data is required. Please complete.' answered with 'unknown at this time ' (Site from System).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:18:41
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:12:40
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:56:46
User entered 'None (NONE)'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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None

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 17:10:17
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'no treatment given' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:56:48
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 04:04:25
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 23:18:56
User entered '1' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:18:56
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Sep 2020 23:12:40
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:56:50
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:56:53
User entered '0'	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'Per CDM: Please provide when it is known.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 03:56:29
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).		02 Nov 2020 22:38:55
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		02 Nov 2020 22:38:42
DataPoint Verified.		31 Oct 2020 00:56:57
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 'no covid results' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:36:18
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'updated' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:36:09
Query 'Per CDM: Please provide when it is known.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:36:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
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)	15 Oct 2020 15:19:29
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		15 Oct 2020 15:16:11

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please provide when it is known.' (Site from DM).	(b) (4), (b) (6)	11 Oct 2020 21:23:31
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' canceled (Site from Safety).		07 Oct 2020 14:45:45
User closed query 'Data is required. Please complete.' (Site from System).		06 Oct 2020 02:09:30
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		02 Oct 2020 14:32:51
Query 'Data is required. Please complete.' answered with 'unknown at this time ' (Site from System).	Yvonne De Los Reyes	16 Sep 2020 23:19:13
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	16 Sep 2020 23:12:40
	Yvonne De Los Reyes	16 Sep 2020 23:12:40
	(b) (4)	

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	31 Oct 2020 00:57:07
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant lab/diagnostic test results (i.e. ESR, pericardial fluid bacteriology and cytology examinations, CBC, Gram stain, AFB, bacteriological cultures). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	03 May 2021 12:46:05
Query 'PV Query: Please provide any relevant lab/diagnostic test results (i.e. ESR, pericardial fluid bacteriology and cytology examinations, CBC, Gram stain, AFB, bacteriological cultures). Please include units and reference ranges if applicable. ' answered with 'records sent ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	30 Apr 2021 20:04:44
User opened query 'PV Query: Please provide any relevant lab/diagnostic test results (i.e. ESR, pericardial fluid bacteriology and cytology examinations, CBC, Gram stain, AFB, bacteriological cultures). Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	5 Apr 2021 21:07:04
User closed query 'Per DM CLR: Narrative = DIAGNOSED WITH PERICARDIAL EFFUSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).		2 Apr 2021 20:10:57
User closed query 'Per DM CLR: Narrative suggests that subject had Pericarditis "DRAINED". However, these are not recorded in the Concomitant Procedure eCRF. Review and record as appropriate. Otherwise, clarify. ' (Site from DM).		2 Apr 2021 05:16:27
User closed query 'PV Query: Please provide amount of pericardial fluid drained.' (Site from Safety).		8 Apr 2021 15:36:47
User closed query 'PV Query: Please provide any relevant lab/diagnostic test results (i.e. ESR, pericardial fluid bacteriology and cytology examinations, CBC, Gram stain, AFB, bacteriological cultures). Please include units and reference ranges if applicable.' (Site from Safety).		8 Apr 2021 15:36:39

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) John McGettigan (b) (4)	08 Apr 2021 15:36:33 08 Apr 2021 12:36:59
Query 'PV Query: Please provide any relevant lab/diagnostic test results (i.e. ESR, pericardial fluid bacteriology and cytology examinations, CBC, Gram stain, AFB, bacteriological cultures). Please include units and reference ranges if applicable.' answered with 'site will submit discharge summary' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:25:19
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'discharge summary will be submitted, recently received ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	08 Apr 2021 03:24:22
Query 'Per DM CLR: Narrative = DIAGNOSED WITH PERICARDIAL EFFUSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Damaris Atondo (b) (4)	08 Apr 2021 02:52:05
Query 'Per DM CLR: Narrative suggests that subject had Pericarditis "DRAINED". However, these are not recorded in the Concomitant Procedure eCRF. Review and record as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	maggie Tono (b) (4)	08 Apr 2021 02:46:04
Query 'PV Query: Please provide amount of pericardial fluid drained.' answered with '300 ml overnight' (Site from Safety).	maggie Tono (b) (4)	08 Apr 2021 02:44:27
User opened query 'Per DM CLR: Narrative = DIAGNOSED WITH PERICARDIAL EFFUSION. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 23:19:37

PRODUCTION RELEASE (v12.003
EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative suggests that subject had Pericarditis "DRAINED". However, these are not recorded in the Concomitant Procedure eCRF. Review and record as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 13:50:18
User opened query 'PV Query: Please provide amount of pericardial fluid drained.' (Site from Safety).		01 Dec 2020 00:25:01
User opened query 'PV Query: Please provide any relevant lab/diagnostic test results (i.e. ESR, pericardial fluid bacteriology and cytology examinations, CBC, Gram stain, AFB, bacteriological cultures). Please include units and reference ranges if applicable.' (Site from Safety).		01 Dec 2020 00:24:49
User closed query 'PV Query: Please provide amount of pericardial fluid drained.' (Site from Safety).		23 Nov 2020 14:29:30
User closed query 'PV Query: Was the subject's pericardial effusion related to an auto-immune disease?' (Site from Safety).		23 Nov 2020 14:29:27
User closed query 'PV Query: Please clarify if the subject had any recent cold/respiratory infections or myocardial ischemia.' (Site from Safety).		23 Nov 2020 14:29:23
User closed query 'PV Query: Please clarify the underlying cause for the pericarditis.' (Site from Safety).		23 Nov 2020 14:29:19
User closed query 'PV Query: Please assess if pericarditis or pericardial effusion meet criteria for reporting as AE/SAEs.' (Site from Safety).		23 Nov 2020 14:29:15
User closed query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' (Site from Safety).		23 Nov 2020 14:29:10
Query 'PV Query: Please clarify the underlying cause for the pericarditis.' answered with 'underlying cause amended' (Site from Safety).	Yvonne De Los Reyes (b) (4)	20 Nov 2020 23:51:15
Query 'PV Query: Please assess if pericarditis or pericardial effusion meet criteria for reporting as AE/SAEs.' answered with 'Per PI, it does not meet reporting criteria but patient was hospitalized greater than 24 hours and per protocol, this is considered an SAE' (Site from Safety).	Yvonne De Los Reyes (b) (4)	20 Nov 2020 23:49:57

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EAB) (1725)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Was the subject's pericardial effusion related to an auto-immune disease? ' answered with 'no, only history of cardiac ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	20 Nov 2020 23:47:52
Query 'PV Query: Please provide amount of pericardial fluid drained.' answered with 'unknown, awaiting medical records ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	20 Nov 2020 23:46:35
Query 'PV Query: Please clarify if the subject had any recent cold/respiratory infections or myocardial ischemia. ' answered with 'patient has not reported any recent cold/respiratory infections or myocardial ischemia ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	20 Nov 2020 23:45:59
Query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' answered with 'Hypertension is recorded in MH and correlates with con med entered ' (Site from Safety).	Yvonne De Los Reyes (b) (4)	20 Nov 2020 23:45:16
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 21:06:12
User opened query 'PV Query: Please provide amount of pericardial fluid drained.' (Site from Safety).		20 Nov 2020 21:05:50
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		13 Nov 2020 13:10:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending records, re-requested' (Site from Safety).	Amanda Hermosillo (b) (4)	12 Nov 2020 21:23:32
User opened query 'PV Query: Was the subject's pericardial effusion related to an auto-immune disease? ' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 12:48:50
User opened query 'PV Query: Please clarify if the subject had any recent cold/respiratory infections or myocardial ischemia. ' (Site from Safety).		12 Nov 2020 12:48:41

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify the underlying cause for the pericarditis.' (Site from Safety).	(b) (4), (b) (6)	12 Nov 2020 12:48:31
User opened query 'PV Query: Please assess if pericarditis or pericardial effusion meet criteria for reporting as AE/SAEs.' (Site from Safety).		12 Nov 2020 12:48:20
User opened query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' (Site from Safety).		09 Nov 2020 18:40:51
User closed query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' (Site from Safety).		02 Nov 2020 22:39:08
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		02 Nov 2020 22:39:06
Query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' answered with 'will update accordingly' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:36:57
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:36:23

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Patient reported he was having chest pain, started on 11sep2020, was seen in the ER on 14sep2020 and diagnosed with Pericardial Effusion, stated it was drained, kept for observation overnight. con meds weren't changed or amended.' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:34:55
User opened query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:19:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		15 Oct 2020 15:19:09
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		15 Oct 2020 15:19:03
Query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' canceled (Site from Safety).		07 Oct 2020 14:45:57
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.' canceled (Site from Safety).		07 Oct 2020 14:45:54
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).		07 Oct 2020 14:45:51

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' canceled (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 14:45:49
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).		06 Oct 2020 02:09:55
User opened query 'PV Query: Hypertension and high blood pressure are both reported as ongoing medical history. Please confirm these are different diagnoses. If the same, please update accordingly.' (Site from Safety).		02 Oct 2020 14:35:56
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		02 Oct 2020 14:35:14
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		02 Oct 2020 14:34:22
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		02 Oct 2020 14:34:12
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered with 'unknown at this time ' (Site from System).	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:19:17
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Sep 2020 23:12:40
User entered empty.	Yvonne De Los Reyes (b) (4)	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Sep 2020 23:12:40

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Sep 2020 23:12:40

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
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)	04 Mar 2021 23:47:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Mar 2021 23:47:43
Data point term sent to Coder	System	04 Mar 2021 23:47:30
User entered 'sore arm post injection'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '12 Feb 2021'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 06:32:46
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:58
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Mar 2021 23:46:53
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User entered empty.	System	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '18 Feb 2021'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 06:32:49
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:47:04
User opened query 'Data is required. Please provide.' (Site from System).	System	04 Mar 2021 23:46:53
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User entered empty.	System	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

US3192614

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Related (RELATED)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Not Related (NOT RELATED)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'I'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	Yvonne De Los Reyes (b) (4)	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User entered '0'	System	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17
User entered '0'	System	04 Mar 2021 23:46:53

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:17

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 18:46:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 18:46:46
Data point term sent to Coder	System	19 Mar 2021 18:45:26
User entered 'fatigue'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User closed query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify. ' (Site from DM).		13 Apr 2021 07:05:50
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
Query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify. ' answered with 'updated' (Site from DM).	maggie Tono (b) (4)	08 Apr 2021 00:39:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 00:38:51
User opened query 'Per DM CLR: Note, this is a solicited adverse reaction per protocol section 8.3.4. Review if this meets AE reporting criteria (i.e., Lasting for more than 7 days post injection) and be reported as a solicited event. If yes, update this field to "YES". Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:59:21
User entered 'No (N)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '30 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	maggie Tono (b) (4)	19 Mar 2021 18:45:37
User entered '3 Sep 2020'	(b) (4)	
	maggie Tono (b) (4)	19 Mar 2021 18:45:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 10:44:06
User opened query 'Data is required. Please provide.' (Site from System).	Yvonne De Los Reyes	24 Mar 2021 14:50:27
User entered empty.	(b) (4)	
	System	19 Mar 2021 18:45:37
	maggie Tono (b) (4)	19 Mar 2021 18:45:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User entered empty.	System	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '6 Oct 2020'	(b) (4) maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	
Query 'Data is required. Please provide.' answered with 'not collected ' (Site from System).	(b) (4), (b) (6)	25 Mar 2021 10:44:07
User opened query 'Data is required. Please provide.' (Site from System).	Yvonne De Los Reyes	24 Mar 2021 14:50:37
User entered empty.	(b) (4)	
	System	19 Mar 2021 18:45:37
	maggie Tono (b) (4)	19 Mar 2021 18:45:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User entered empty.	System	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Grade 1/Mild (Grade 1/Mild)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'No (N)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

US3192614

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

US3192614

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

US3192614

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	(b) (4) maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Not Related (NOT RELATED)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Related (RELATED)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'None (NONE)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'I'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered '0'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	(b) (4) maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 12:36:59
User entered empty.	maggie Tono (b) (4)	19 Mar 2021 18:45:03

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User entered '0'	System	19 Mar 2021 18:45:03

US3192614

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20
User entered '0'	System	19 Mar 2021 18:45:03

US3192614

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:45:33

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 00:02:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:45:33

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:29:37
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	maggie Tono (b) (4)	06 Sep 2020 15:32:48

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: ANTIARRHYTHMICS, CLASS I AND III, ATC: ANTIARRHYTHMICS, CLASS III, PRODUCT: AMIODARONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 18:34:37
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 18:34:37
Data point term sent to Coder	System	06 Sep 2020 15:35:12
User entered 'amiodarone'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 04:04:05
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'updated medical history page ' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:44:36
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:32:22
User entered 'ventricular fibrillation/tachycardia'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '200'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Apr 2018'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:34:56

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIPIZIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Sep 2020 20:14:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 20:14:34
Data point term sent to Coder	System	06 Sep 2020 15:36:13
User entered 'glipizide er'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'diabetes'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '2.5'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:36:10

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 00:38:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Oct 2020 00:38:04
Data point term sent to Coder	System	31 Oct 2020 00:37:25
Coding entries removed.	Yvonne De Los Reyes	31 Oct 2020 00:37:15
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:39:35
Data point term sent to Coder	System	06 Sep 2020 15:38:16
User entered 'Tamsulosin'	maggie Tono (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 17:21:24
Query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:37:20
User entered 'Hypertension' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:37:15
User opened query 'Per DM CLR: Please review the indication of this medication as this is not the expected use for this medication. Either change the indication or provide explanation for alternate/different use. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:32:43
User entered 'high blood pressure'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0.4'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Apr 2018'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:37:28

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 15:39:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:39:35
Data point term sent to Coder User entered 'Lipitor'	System maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:13 06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'high cholesterol'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '80'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Feb 2011'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:38:07

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), COMBINATIONS, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS) AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE;LOSARTAN POTASSIUM, PRODUCTSYNONYM: LOSARTAN/HCTZ - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:42:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:42:35
Data point term sent to Coder User entered 'losartan/hctz'	System maggie Tono (b) (4)	06 Sep 2020 15:42:17 06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'hypertension'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 04:05:21
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated to reflect source ' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:42:00
User entered '100/125' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:41:54
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:33:13
User entered '1000/125'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Feb 2011'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:42:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE HYDROCHLORIDE, PRODUCTSYNONYM: OXYCONTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Sep 2020 12:38:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 12:38:42
Data point term sent to Coder	System	06 Sep 2020 15:43:18
User entered 'oxycontin'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'osteoarthritis'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '30'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'as needed (PRN)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 04:06:23
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.' answered with 'updated to reflect source ' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:41:21
User entered 'UN Feb 2010' reason for change: Data Entry Error	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:41:10
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.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:33:44
User entered 'un Jan 2010'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Sep 2020 15:43:15

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: ALPRAZOLAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:46:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:46:35
Data point term sent to Coder	System	06 Sep 2020 15:45:20
User entered 'alprazolam'	maggie Tono (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 03:40:45
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'med hx page updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:38:33
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:34:19
User entered 'anxiety'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0.5'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Feb 2018'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:44:25

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:46:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:46:35
Data point term sent to Coder User entered 'adderrall'	System maggie Tono (b) (4)	06 Sep 2020 15:46:20 06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Nov 2020 03:41:59
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'med hx page updated ' (Site from DM).	Yvonne De Los Reyes (b) (4)	31 Oct 2020 00:39:39
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:34:34
User entered 'Attention deficit disorder'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '30'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'once daily (QD)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Feb 2018'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:46:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Sep 2020 15:48:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:48:36
Data point term sent to Coder	System	06 Sep 2020 15:47:21
User entered 'metformin'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'diabetes'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '1000'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:46:40

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: DULOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Sep 2020 15:49:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:49:36
Data point term sent to Coder	System	06 Sep 2020 15:48:21
User entered 'duloxetine'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'osteoarthritis'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '60'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'once daily (QD)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:47:45

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: COREG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Sep 2020 15:50:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:50:36
Data point term sent to Coder User entered 'coreg'	System maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:21 06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'hypertension'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '12.5'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'once daily (QD)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Feb 2011'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:48:46

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Sep 2020 15:51:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:51:36
Data point term sent to Coder	System	06 Sep 2020 15:50:22
User entered 'gabapentin'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please update the indication to reflect the location of NERVE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:56:20
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).		17 Nov 2020 10:56:17
Query 'Per DM CLR: Please update the indication to reflect the location of NERVE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Amanda Hermosillo (b) (4)	12 Nov 2020 21:33:28
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'updated' (Site from DM).	Amanda Hermosillo (b) (4)	12 Nov 2020 21:33:19
User opened query 'Per DM CLR: Please update the indication to reflect the location of NERVE PAIN. Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 06:39:27
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).		20 Oct 2020 09:48:28
User entered 'nerve pain'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '300'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'other (OTHER)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '6x a day'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
	(b) (4)	
User entered '0'	maggie Tono (b) (4)	06 Sep 2020 15:49:48
	(b) (4)	

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Sep 2020 15:49:48

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: SILDENAFIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:51:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Sep 2020 15:51:36
Data point term sent to Coder	System	06 Sep 2020 15:51:22
User entered 'Sildenafil'	maggie Tono (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (D) (4), (b) (6)	17 Nov 2020 10:56:44
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'updated' (Site from DM).	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:04
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:34:47
User entered 'erectile dysfunction'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '20'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:50:55

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: TIZANIDINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Sep 2020 15:53:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Sep 2020 15:53:36
Data point term sent to Coder	System	06 Sep 2020 15:52:23
User entered 'tizanidine'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 10:57:10
Query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' answered with 'updated' (Site from DM).	Amanda Hermosillo (b) (4)	12 Nov 2020 21:34:58
User opened query 'Per DM CLR: Please note that there is no MedHistory Condition that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the MedHistory eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:35:01
User entered 'muscle spasm'	maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '4'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'twice daily (BID)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'un Jan 2015'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '0'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) maggie Tono (b) (4) (b) (4)	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Sep 2020 15:51:47

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Sep 2020 09:48:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Sep 2020 09:48:35
Data point term sent to Coder	System	26 Sep 2020 17:45:50
User entered 'IBUPROFEN'	Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
	(b) (4)	
User entered 'No (N)'	Crystal Mata (b) (4)	26 Sep 2020 17:45:08
	(b) (4)	

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Nov 2020 08:16:43
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON INJECTION SITE did not meet the AE reporting criteria.' answered with 'IBUPROFEN WAS TAKEN ON VISIT 1 DAY 1. PAIN ON INJECTION SITE DOES NOT MEET AE REPORTING CRITERIA.' (Site from DM).	Crystal Mata (b) (4) (b) (4)	18 Nov 2020 02:15:37

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN ON INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN ON INJECTION SITE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 07:35:41
User entered 'PAIN ON INJECTION SITE'	Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '400'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'mg (mg)'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'as needed (PRN)'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
	(b) (4)	
User entered empty.	Crystal Mata (b) (4)	26 Sep 2020 17:45:08
	(b) (4)	

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Oral (ORAL)'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '31 Aug 2020'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
	(b) (4)	
User entered '0'	Crystal Mata (b) (4)	26 Sep 2020 17:45:08
	(b) (4)	

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'Yes (Y)'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered empty.	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) Crystal Mata (b) (4) (b) (4)	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:45:33

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Sep 2020 17:45:08

US3192614

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:45:33

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered 'No (N)'	(b) (4) Norma Barrientos (b) (4)	27 Sep 2020 18:47:51
	(b) (4)	

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '17/Sep/2020 11:52'	(b) (4) System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 14:00:14
User entered 'I'		17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (D) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '24/Sep/2020 10:00'	(b) (4) System	24 Sep 2020 14:00:26

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	07 Oct 2020 14:48:53
User entered 'I'		24 Sep 2020 14:00:26

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (d) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '07/Oct/2020 14:49'	(b) (4) System	07 Oct 2020 14:49:09

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Oct 2020 14:28:07
User entered 'I'		07 Oct 2020 14:49:09

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '12/Oct/2020 14:28'	(b) (4) System	12 Oct 2020 14:28:27

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	02 Nov 2020 22:39:28
User entered 'I'		12 Oct 2020 14:28:27

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '02/Nov/2020 22:39'	(b) (4) System	02 Nov 2020 22:39:38

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	13 Nov 2020 16:06:23
User entered 'I'		02 Nov 2020 22:39:38

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '13/Nov/2020 11:06'	(b) (4) System	13 Nov 2020 16:06:33

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (d) (4), (b) (6)	23 Nov 2020 14:29:42
User entered 'I'		13 Nov 2020 16:06:33

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '23/Nov/2020 14:29'	(b) (4) System	23 Nov 2020 14:29:56

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 15:56:19
User entered 'I'		23 Nov 2020 14:29:56

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
User entered '15/Mar/2021 11:56'	(b) (4) System	15 Mar 2021 15:56:16

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
Reviewed for Safety.	(b) (4) (D) (4), (b) (6)	15 Mar 2021 15:56:19
User entered 'I'		15 Mar 2021 15:56:16

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:41
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'USA-US097-2020-MRNA-1273-P301000002'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

Serious

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:43
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:45
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:56
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:58
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Yes (Y)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:32:59
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:01
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:02
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'No (N)'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:05
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'John'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:06
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'McGettigan'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:08
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '5390 E. Erickson Drive'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:10
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'Tucson'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:11
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered 'AZ'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:13
Reviewed for Safety.		17 Sep 2020 15:52:43
User entered '85712'	System	17 Sep 2020 15:51:58

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 01:24:40
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 22:33:14
Reviewed for Safety.		24 Sep 2020 14:00:14
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 08:51:19
User entered 'US' (non-conformant).	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form

Generated On: 09 Jun 2021 15:45:33

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	08 Apr 2021 15:02:39
User entered '8'	System	15 Mar 2021 15:56:16
User entered '7'	System	23 Nov 2020 14:29:56
User entered '6'	System	13 Nov 2020 16:06:33
User entered '5'	System	02 Nov 2020 22:39:38
User entered '4'	System	12 Oct 2020 14:28:27
User entered '3'	System	07 Oct 2020 14:49:09
User entered '2'	System	24 Sep 2020 14:00:26
User entered '1'	System	17 Sep 2020 15:52:51

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:45:33

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	John McGettigan (b) (4)	08 Apr 2021 19:45:03
User entered '08/Apr/2021 11:02'	(b) (4) System	08 Apr 2021 15:02:39

US3192614

Folder: SAE USA-US097-2020-MRNA-1273-P301000002

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:45:33

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.	John McGettigan (b) (4)	08 Apr 2021 19:45:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	08 Apr 2021 15:02:39