

US3172185 (Prod: Suncoast Research Group LLC - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:31:03

All time stamps listed in this document are displayed in GMT

US3172185

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

Participant ID

US3172185

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

US3172185

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	18 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3172185

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Date of Birth (MMM yyyy)	(b) (6) 1958
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input 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) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Date of Informed Consent (*dd MMM yyyy*) 18 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3172185

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172185

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172185

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	OBESE
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172185

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	MITRLA VALVE REPLACEMENT
Start date (dd MMM yyyy)	UN DEC 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	PNEUMONIA SECONDARY TO COVID19
Start date (dd MMM yyyy)	04 JUL 2020
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)	26 JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	MITRAL VALVE REGURGITATION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	DEC 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	CHRONIC HEART FAILURE
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	ATRIAL FIBRILLATION
Start date (dd MMM yyyy)	UN DEC 2017
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)	DEC 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	COVID 19 INFECTION
Start date (dd MMM yyyy)	04 JUL 2020
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)	18 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	RHEUMATOID ARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	ANEMIA
Start date (dd MMM yyyy)	UN UNK 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN JUL 2020
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JUL 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	HEARTBURN
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 28 Apr 2021 07:33:46

Generated On: 09 Jun 2021 15:31:03

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2020
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 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3172185

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 12:00
Height (xxx.x)	170.6 cm
Weight (xxx.x)	108.4 kg
BMI (xxx.x)	37.24528 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

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: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

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

CONSTRUCTION WORKER

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) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

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) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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

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

Folder OID	VISIT1
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US3172185

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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

What was the participant's randomization number? 144236

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 ☒

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Height	ND - Not Done
Weight	ND - Not Done

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 12:00
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 AUG 2020
Time of assessment (00:00-23:59)	16:05 (24 HR)
Vital Signs Date and Time (derived)	18 AUG 2020 16:05
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Was study treatment given? Yes ☒
No ☐

If No, reason not given

Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:42 (24 HR)

Treatment Date and Time (derived) 18 AUG 2020 15:42

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) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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

Collection date (dd MMM yyyy)	18 AUG 2020
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Collection time (00:00-23:59)	15:34 (24 HR)
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Collection date and time (derived)	18 AUG 2020 15:34
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Collection date (dd MMM yyyy)			18 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:28	18 AUG 2020 15:28
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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

98.8 °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

18 AUG 2020 16:29

PC Open Date & Time

18 AUG 2020 16:02

PC Close Date & Time

18 AUG 2020 18:32

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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	18 AUG 2020 19:44
PC Open Date & Time	18 AUG 2020 19:27
PC Close Date & Time	19 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 17:30

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 18:26

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 18:41

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 02:59

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 16:40

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 18:47

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 16:30

PC Open Date & Time

18 AUG 2020 16:02

PC Close Date & Time

18 AUG 2020 18:32

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 AUG 2020 19:46

PC Open Date & Time

18 AUG 2020 19:27

PC Close Date & Time

19 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 AUG 2020 17:30

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

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

20 AUG 2020 18:27

PC Open Date & Time

20 AUG 2020 12:00

PC Close Date & Time

21 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 18:42

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 5

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 03:00

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 16:41

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 18:48

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 16:31
PC Open Date & Time	18 AUG 2020 16:02
PC Close Date & Time	18 AUG 2020 18:32

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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

No ☒

Yes ☐

PC Time stamp	18 AUG 2020 19:47
PC Open Date & Time	18 AUG 2020 19:27
PC Close Date & Time	19 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

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)

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 17:31
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

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

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EAB) (1725)

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

Yes <input type="checkbox"/>	
PC Time stamp	20 AUG 2020 18:28
PC Open Date & Time	20 AUG 2020 12:00
PC Close Date & Time	21 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 18:42
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2603

EAB) (1725)

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 03:01
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

66 of 2603

EAB) (1725)

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 16:42
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

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 ☒

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 18:49
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3172185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 26 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 02 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3172185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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.

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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 DUE TO SAE ACUTE CHEST PRESSURE

What was the study treatment? _____

What was the treatment date? (dd MMM yyyy) _____

What was the treatment time? (00:00-23:59) _____

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3172185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Collection date (dd MMM yyyy)

Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	No		

US3172185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 24 SEP 2020

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

Comments
UNABLE TO CONTACT
SUBJECT. LEFT VOICEMAIL TO
CALL SITE BACK.

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:53:23

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments UNABLE TO CONTACT

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:53:23

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments UNABLE TO CONTACT

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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

Visit date (dd MMM yyyy)	14 OCT 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT3
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US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	14 OCT 2020
Time of assessment (<i>00:00-23:59</i>)	08:21 (24 HR)
Vital Signs Date and Time (derived)	14 OCT 2020 08:21
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	71 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

14 OCT 2020

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

US3172185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

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

Collection date (dd MMM yyyy)	14 OCT 2020
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Collection time (00:00-23:59)	09:52 (24 HR)
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Collection date and time (derived)	14 OCT 2020 09:52
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US3172185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:38

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 OCT 2020 13:11:24

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

01 NOV 2020 00:01

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

26 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Patient Cloud Open Date & Time	10 DEC 2020 00:01
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Patient Cloud Close Date & Time	14 DEC 2020 23:59
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US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

17 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2020 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Patient Cloud Open Date & Time	24 DEC 2020 00:01
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Patient Cloud Close Date & Time	28 DEC 2020 23:59
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US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

31 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

14 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 159

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

21 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had 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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

08 FEB 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 FEB 2021 16:07:03

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

08 MAR 2021 18:11:21

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 15:42:57

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 18:50:07

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

29 MAR 2021 19:11:01

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 17:50:43

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 07:15:47

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

22 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 02:50:29

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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°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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 <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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Patient Cloud Open Date & Time	12 AUG 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

19 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 <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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Patient Cloud Open Date & Time	26 AUG 2021 00:01
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Patient Cloud Close Date & Time	30 AUG 2021 23:59
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US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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°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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

02 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

16 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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="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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

02 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 <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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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°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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

03 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

07 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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="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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAY 2022 00:01
Patient Cloud Close Date & Time	16 MAY 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

19 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

26 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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="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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 AUG 2022 00:01
Patient Cloud Close Date & Time	15 AUG 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Date and time of submission

Patient Cloud Open Date & Time	18 AUG 2022 00:01
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Patient Cloud Close Date & Time	22 AUG 2022 23:59
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US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Patient Cloud Open Date & Time	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Date and time of submission	
Patient Cloud Open Date & Time	01 SEP 2022 00:01
Patient Cloud Close Date & Time	05 SEP 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 <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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 <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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Open Date & Time](#)

22 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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="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"/>

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
Patient Cloud Close Date & Time	24 OCT 2022 23:59

US3172185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:31:03

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		03 MAR 2021 18:09:46

US3172185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 03 Mar 2021 13:53:23

Generated On: 09 Jun 2021 15:31:03

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 MISSED

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 16:18:37

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 17 Feb 2021 14:16:36

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 17 Feb 2021 14:16:36

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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

Visit date (dd MMM yyyy)	12 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 APR 2021
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 08:52
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3172185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3172185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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

Collection date (dd MMM yyyy)	12 APR 2021
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Collection time (00:00-23:59)	11:04 (24 HR)
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Collection date and time (derived)	12 APR 2021 11:04
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US3172185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172185

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:31:03

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"/>

US3172185

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:31:03

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3172185

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

Form: Visit Date

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Was this visit performed? Yes ☒
No ☐

Visit date (dd MMM yyyy) 10 MAR 2021

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

Folder OID UNBLND_DECIDE

US3172185

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

Form: Unblinding

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Date of updated informed consent (<i>dd MMM yyyy</i>)	06 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>)	10 MAR 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

US3172185

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Height	ND - Not Done
Weight	115.8 kg
BMI (xxx.x)	

US3172185

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Height	ND - Not Done
Weight	115.8 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 MAR 2021
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 08:05
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3172185

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Height	ND - Not Done
Weight	115.8 kg
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 MAR 2021
Time of assessment (00:00-23:59)	11:38 (24 HR)
Vital Signs Date and Time (derived)	10 MAR 2021 11:38
Temperature (xxx.x)	37.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3172185

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

Form: Physical Examination

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Was the physical examination performed?

Yes ☒
No ☐

Date of examination (dd MMM yyyy)

10 MAR 2021

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

US3172185

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

Form: Exposure

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

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) 10 MAR 2021

What was the treatment time? (00:00-23:59) 11:08 (24 HR)

Treatment Date and Time (derived) 10 MAR 2021 11:08

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

US3172185

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Was the sample collected? Yes ☒
No ☐

Collection date (dd MMM yyyy) 10 MAR 2021

Collection time (00:00-23:59) 09:57 (24 HR)

Collection date and time (derived) 10 MAR 2021 09:57

US3172185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 MAR 2021
Collection time (00:00 - 23:59)	09:58
Collection Date and Time (derived)	10 MAR 2021 09:58

US3172185

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

Form: Continuing

Data signed: (b) (4) 12 Mar 2021 20:13:04

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3172185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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

Visit date (dd MMM yyyy)	12 APR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	OLD29
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US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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)	12 APR 2021
Time of assessment (00:00-23:59)	08:52 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 08:52
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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)	12 APR 2021
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	12 APR 2021 12:00
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	74 mmHg
Diastolic Blood Pressure units	MMHG

US3172185

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 APR 2021

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

US3172185

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

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) 12 APR 2021

What was the treatment time? (00:00-23:59) 11:30 (24 HR)

Treatment Date and Time (derived) 12 APR 2021 11:30

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

US3172185

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 16:23:28

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3172185

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3172185

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

AEID	USA-US118-2020-MRNA-1273-P30 1000003
Adverse event	NON CARDIAC CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	07 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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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

ACUTE CHEST PRESSURE
ASSOCIATED WITH TO
DYSPNEA ON EXERTION AND
FATIGUE STARTING ON
09SEP2020. SUBJECT WENT TO
ER ON 07SEP2020 WHERE HE
WAS ADMITTED. STILL IN
HOUSE. HE UNDERWENT AN
EGD TO RULE OUT GI CAUSES
AND A CARDIAC CATHETER
TODAY TO RULE OUT CV
CAUSES (OTHERS).
INFORMATION GATHERED BY
PHONE DIRECTLY FROM
SUBJECT. WILL REQUEST
HOSPITALIZATION RECORDS
WHEN SUBJECT IS
DISCHARGED HOME. HE IS
RECOVERING. THE EVENT
MEET SAE CRITERIA AND
DETAILS RELATED TO THE
EVENT WILL BE PROVIDED
WHEN MR'S ARE AVAILABLE.
SUBJECT HAD
TRANSESESOPHAGEAL
ECHOCARDIOGRAM ON
11SEP2020 (NO EGD) FINDINGS:
ARE SUGGESTIVE OF
PROSTHETIC MITRAL VALVE
STENOSIS. TRACE PULMONIC
VALVULAR REGURGITATION.
THERE IS TRACE TRICUSPID
REGURGITATION. MILD
ATHEROSCLEROTIC PLAQUE(S)
IN THE DESCENDING

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

AORTA.BIOPROSTHETIC
MITRAL VALVE STENOSIS.
CARDIAC CATHETERIZATION
DONE ON 14SEP2020 FINDINGS:
1. MILD MITRAL VALVE
STENOSIS, GRADIENT ACROSS
THE MITRAL VALVE OF ONLY
4MMHG, CALCULATED MITRAL
VALVE AREA 2.17 SQ CM. THIS
REPRESENTS NORMAL
HEMODYNAMICS FOR THIS
BIOPROSTHETIC VALVE. 2. NO
EVIDENCE OF OBSTRUCTIVE
CORONARY ARTERY DISEASE.
3.NORMAL CARDIAC OUTPUT
AND CARDIAC INDEX.
4.NORMAL RIGHT-SIDED
CARDIAC PRESSURE. ADULT
ECHO DONE ON 09SEP2020,
FINDINGS: LEFT VENTRICULAR
SYSTOLIC FUNCTION IS MILD
TO MODERATELY REDUCED.
THE RIGHT VENTRICULAR
SYSTOLIC FUNCTION IS MILD
TO MODERATELY REDUCED.
MILD TO MODERATE
VALVULAR AORTIC
STENOSIS. GRADIENT ARE
ABNORMAL FOR THIS
PROTHETIC MITRAL
VALVE.LAB DONE ON
07SEP2020: PH 7.44, HCF03
32MMOL/L, BASE EXCESS
8MMOL/L, HGB 02 SAT VEN
77.0%, APTT 41 SECONDS,

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

POTASSIUM 3.2MMOL/L,
TOTAL C02 CONTENT
40MMOL/L, ANION GAP <2,
NT-PROBNP 3,410.0 PG/ML,
HEMOGLOBIN 9.0 G/DL,
HEMATOCRIT 31.2%, MCH 25.9
PG, MCHC 28.8 G/DL, RDW-CV
17.5%. LAB DONE ON 14SEP2020:
HEMOGLOBIN 11.8 G/DL RANGE:
13.3-16.3, HEMATOCRIT 38.9%
RANGE: 39.0-47.1

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

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

AEID	USA-US118-2020-MRNA-1273-P30 1000003
Adverse event	ACUTE EXACERBATION OF SYSTOLIC HEART FAILURE
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)	7 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 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 (2)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

SUBJECT OF HISTORY OF
CHRONIC HEART FAILURE
WITH SEVERAL EPISODES OF
EXACERBATION IN THE LAST 2
YEARS SECONDARY TO
MITRAL VALVE REPLACEMENT
WITH PROSTHETIC
REPLACEMENT IN 2017 AND
RESTENOSIS SINCE LAST YEAR.

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

US3172185

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

AEID	USA-US118-2020-MRNA-1273-P30 1000003
Adverse event	ATRIAL FIBRILATION WITH RAPID VENTRICULAR RATE
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)	7 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 checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	7 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 (3)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WITH HISTORY OF ATRIAL FIBRILLATION SINCE 2017 AFTER MITRAL VALVE REPLACEMENT DUE TO MITRAL VALVE REPLACEMENT HISTORY WITH RECENT RESTENOSIS.

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

AEID

Adverse event

SUPRATHERAPEUTIC
INTERNATIONAL NORMALIZED
RATIO (INCREASED)

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) 7 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐
No ☒

If not Ongoing, end date (dd MMM yyyy) 11 SEP 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☐
Grade 2/Moderate ☒
Grade 3/Severe ☐
Grade 4 ☐

Is the adverse event serious? Yes ☐
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐
No ☐
Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Feb 2021 16:18:35

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 16:18:36

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE 2

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 (2)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	21 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		11 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE /
ATRIAL FIBRILLATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)	23 DEC 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication COUMADIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 1.75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)	11 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		UN JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication AMIODARONE

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RHEUMATOID ARTHRITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication CANDESARTAN

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE - CHF

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)	07 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication ENOXAPARIN

Prophylaxis Yes ☐
No ☒

Indication ATRIAL FIBRILLATION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

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 (10)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 11 SEP 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)	11 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)		23 DEC 2017
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEART FAILURE /
ATRIAL FIBRILLATION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)	23 DEC 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication LABETALOL

Prophylaxis Yes ☐
No ☒

Indication ACUTE CHRONIC HEART
FAILURE

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	07 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		07 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

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 (15)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)	11 SEP 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)	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 (16)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication CHOLESTEROL

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication ENTRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 24/26

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 (17)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication SEROQUEL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC HEAT FAILURE

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication CRESTOR

Prophylaxis Yes ☐
No ☒

Indication HYPOCHOLESTEROLEMIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

AT BEDTIME

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication ELIQUIS

Prophylaxis Yes ☐
No ☒

Indication AFIB

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RHEUMATISMS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

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

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication WASFASIN

Prophylaxis Yes ☐
No ☒

Indication AFIB

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	07 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication PREDNISONE

Prophylaxis Yes ☐
No ☒

Indication RHEUMATISMS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2017
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 26 MAR 2021		
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	803 <input type="radio"/>
	804 <input checked="" type="radio"/>	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication FEERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication METROPOLOL

Prophylaxis Yes ☐
No ☒

Indication CHF/AFIB

Dose per administration 325/50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 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 (27)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	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)		11 SEP 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

Name of Medication INSULIN LISPRO

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration SLIDING SCALE

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

If dose unit is Other, specify SLIDING SCALE UNIT

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 (28)

Data signed: (b) (4) 22 Apr 2021 16:23:27

Generated On: 09 Jun 2021 15:31:03

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		15 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	TRANSESESOPHAGEAL ECHOCARDIOGRAM	Adverse Event	
14 SEP 2020	CARDIAC CATHETERIZATION	Adverse Event	
09 SEP 2020	ADULT ECHOCARDIOGRAM (AE 2D ECHO	Adverse Event	
7 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	
11 SEP 2020	CHEST X-RAY	Adverse Event	
7 SEP 2020	CHEST X-RAY	Adverse Event	

US3172185

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

Date of dosing discontinuation (dd MMM yyyy) 14 SEP 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input checked="" type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify SAE #1

US3172185

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:31:03

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 ☐

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13

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Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	15/SEP/2020 13:33
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.	True

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	29/SEP/2020 09:17
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	30/SEP/2020 13:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	19/OCT/2020 15:47
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	21/OCT/2020 13:51
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	22/OCT/2020 13:25
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	23/OCT/2020 12:55
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	26/OCT/2020 11:15
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	05/NOV/2020 10:26
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	16/NOV/2020 11:26
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	18/NOV/2020 15:13
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	25/NOV/2020 18:03
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

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (13)

Data signed: (b) (4) 16 Feb 2021 16:18:36

Generated On: 09 Jun 2021 15:31:03

SAEID	USA-US118-2020-MRNA-1273-P301000003
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	MARK
Investigator's Last Name	KUTNER
Site Address: Street	
Site Address: City	
Site Address: State	FL
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	13
Date of submission (Pre-filled from custom function)	25/NOV/2020 18:03
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

US3172185 (Prod: Suncoast Research Group LLC - ERN-PPDS)

US3172185

Form: Participant Creation

Generated On: 09 Jun 2021 15:31:03

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'US3172185'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:04:39

US3172185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:57:18

US3172185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:04:40

US3172185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[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 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4)	18 Aug 2020 19:57:18
	(b) (4)	

US3172185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'SCRN'	System	18 Aug 2020 19:57:18

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered (b) (6) 1958'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:04:41

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '61'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'YEARS'	System	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '61'	System	18 Aug 2020 19:49:02

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Male (M)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:44
	(b) (4)	

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:44
	(b) (4)	

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:44
	(b) (4)	

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 19:59:44
	(b) (4)	

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:31:03

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:44

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '18 Aug 2020'	Mariete Rendon (b) (4)	18 Aug 2020 19:49:02
	(b) (4)	

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Aug 2020'	System	18 Aug 2020 19:49:02

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	18 Aug 2020 19:49:02

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Amendment 1 (1)' reason for change:	Mariete Rendon (b) (4)	01 Oct 2020 21:28:57
Data Entry Error	(b) (4)	
User entered 'Amendment 2 (2)'	Mariete Rendon (b) (4)	18 Aug 2020 19:49:02
	(b) (4)	

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:02

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 19:49:02
	(b) (4)	

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:02

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Aug 2020 19:49:02
	(b) (4)	

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:04:40

US3172185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:31:03

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'I'	System	18 Aug 2020 19:49:07

US3172185

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	18 Aug 2020 19:49:07
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:31:03

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:06:16

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Presbyopia, LLT: Presbyopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:04
Data point term sent to Coder	System	18 Aug 2020 20:08:01
User entered 'PRESBYOPIA'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2015'	System	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2015'	System	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:07:12

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Vascular disorders, HLTG: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:03
Data point term sent to Coder	System	18 Aug 2020 20:08:01
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2017'	System	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:07:28

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Umbilical hernias, PT: Umbilical hernia, LLT: Umbilical hernia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:03
Data point term sent to Coder	System	18 Aug 2020 20:08:01
User entered 'UNBILICAL HERNIA'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'UN UNK 2015'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2015'	System	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2015'	System	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:07:52

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:05
Data point term sent to Coder	System	18 Aug 2020 20:09:02
User entered 'DIABETES TYPE 2'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'UN UNK 2017'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2017'	System	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:08:11

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Appetite and general nutritional disorders, HLT: General nutritional disorders NEC, PT: Obesity, LLT: Obesity - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Aug 2020 23:30:05
Data point term sent to Coder	System	18 Aug 2020 20:09:03
User entered 'OBESE'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'UN UNK 2008'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 20:08:35
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2008'	System	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2008'	System	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	18 Aug 2020 20:08:35

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral valve insufficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 21:16:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Sep 2020 21:16:46
Data point term sent to Coder	System	14 Sep 2020 21:15:56
User entered 'mitral valve insufficiency'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un UNK 2016'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un UNK 2016'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2016'	System	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2016'	System	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2016'	System	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2016'	System	14 Sep 2020 21:15:36

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Surgical and medical procedures, HLGT: Cardiac therapeutic procedures, HLT: Cardiac valve therapeutic procedures, PT: Mitral valve replacement, LLT: Mitral valve replacement - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:19:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Sep 2020 06:19:41
Data point term sent to Coder	System	14 Sep 2020 21:16:59
User entered 'mitrla valve replacement'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'UN Dec 2017' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:30:52
User entered 'un UNK 2016'	Mariete Rendon (b) (4)	14 Sep 2020 21:16:08
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'UN Dec 2017' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:30:52
User entered 'un UNK 2016'	Mariete Rendon (b) (4)	14 Sep 2020 21:16:08
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Dec 2017'	System	20 Oct 2020 13:30:52
User entered 'Jan 2016'	System	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	20 Oct 2020 13:30:52
User entered '2016'	System	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Dec 2017'	System	20 Oct 2020 13:30:52
User entered 'Jan 2016'	System	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	20 Oct 2020 13:30:52
User entered '2016'	System	14 Sep 2020 21:16:08

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per MM: Please confirm if the subject received prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19 (EC#4). If so, please report as possible PD.' (Site from DM). Query 'Per MM: Please confirm if the subject received prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19 (EC#4). If so, please report as possible PD.' answered with 'No, only 1st dose of MRNA 1273 (Moderna). Confirmed with subject ' (Site from DM).	(b) (4), (b) (6) Jessie Downs (b) (4) (b) (4)	19 Nov 2020 15:44:13 17 Nov 2020 17:56:02
User opened query 'Per MM: Please confirm if the subject received prior administration of an investigational coronavirus (SARS-CoV, MERS-CoV) vaccine or current/planned simultaneous participation in another interventional study to prevent or treat COVID-19 (EC#4). If so, please report as possible PD.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 13:56:38
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19 pneumonia, LLT: COVID-19 pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 11:19:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	09 Nov 2020 11:19:29
Data point term sent to Coder	System	20 Oct 2020 13:26:54
User entered 'Pneumonia secondary to COVID19'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '04 Jul 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '26 Jul 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jul 2020'	System	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jul 2020'	System	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	20 Oct 2020 13:26:09

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve stenosis, LLT: Mitral valve stenosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:21:04
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 00:21:04
Data point term sent to Coder	System	20 Oct 2020 13:27:55
User entered 'mitral valve restenosis'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'un UNK 2019'	Mariete Rendon (b) (4)	20 Oct 2020 13:27:30
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:27:30
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:27:30
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2019'	System	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2019'	System	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:27:30

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Cardiac disorders, HLT: Cardiac valve disorders, HLT: Mitral valvular disorders, PT: Mitral valve incompetence, LLT: Mitral regurgitation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:29:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:29:31
Data point term sent to Coder	System	20 Oct 2020 13:28:56
User entered 'mitral valve regurgitation'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un UNK 2016'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'un Dec 2017'	Mariete Rendon (b) (4)	20 Oct 2020 13:28:27
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:28:27
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2016'	System	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2016'	System	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Dec 2017'	System	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	20 Oct 2020 13:28:27

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure chronic, LLT: Chronic heart failure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:29:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:29:32
Data point term sent to Coder	System	20 Oct 2020 13:28:56
User entered 'chronic heart failure'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un UNK 2017'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:28:51
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2017'	System	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:28:51

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:30:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:30:41
Data point term sent to Coder	System	20 Oct 2020 13:29:58
User entered 'atrial fibrillation'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un Dec 2017'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:29:20
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:29:20
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:29:20
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Dec 2017'	System	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:29:20

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per MM: Please confirm if this subject received prior IP vaccine for SARS-CoV, MERS-CoV. If yes, please report as possible protocol deviation (EC#4)' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 15:44:41
Query 'Per MM: Please confirm if this subject received prior IP vaccine for SARS-CoV, MERS-CoV. If yes, please report as possible protocol deviation (EC#4)' answered with 'No, only 1st dose of MRNA-1273 (Moderna). Confirmed with subject.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	17 Nov 2020 17:58:34
User opened query 'Per MM: Please confirm if this subject received prior IP vaccine for SARS-CoV, MERS-CoV. If yes, please report as possible protocol deviation (EC#4)' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 13:55:47
User coded data point as SOC: Infections and infestations, HLT: Viral infectious disorders, HLT: Coronavirus infections, PT: COVID-19, LLT: COVID-19 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:33:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:33:34
Data point term sent to Coder	System	20 Oct 2020 13:32:00
User entered 'COVID 19 Infection'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '04 Jul 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jul 2020'	System	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Aug 2020'	System	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	20 Oct 2020 13:31:46

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Rheumatoid arthropathies, PT: Rheumatoid arthritis, LLT: Rheumatoid arthritis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:33:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 13:33:36
Data point term sent to Coder	System	20 Oct 2020 13:33:02
User entered 'rheumatoid arthritis'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un UNK 2000'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:32:27
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2000'	System	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2000'	System	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	20 Oct 2020 13:32:27

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Anaemia, LLT: Anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 18:24:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Dec 2020 18:24:23
Data point term sent to Coder	System	16 Dec 2020 18:22:49
User entered 'anemia'	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'un UNK 2017'	Jessie Downs (b) (4)	16 Dec 2020 18:22:31
	(b) (4)	

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'un Jul 2020'	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2017'	System	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2017'	System	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jul 2020'	System	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	16 Dec 2020 18:22:31

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Heartburn - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:55:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:55:00
Data point term sent to Coder	System	22 Apr 2021 18:54:08
User entered 'heartburn'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'un UNK 2008'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '0'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '0'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2008'	System	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2008'	System	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	22 Apr 2021 18:54:01

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:56:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Apr 2021 18:56:02
Data point term sent to Coder	System	22 Apr 2021 18:55:09
User entered 'hypercholesterolemia'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'un UNK 2020'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '0'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	28 Apr 2021 07:33:47
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '0'	Jessie Downs (b) (4) (b) (4)	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'Jan 2020'	System	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '2020'	System	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 08:54:30
Data hard unlocked.	(b) (4), (b) (6)	29 Apr 2021 09:39:25
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	22 Apr 2021 18:54:21

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '18 Aug 2020'	Mariete Rendon (b) (4)	18 Aug 2020 20:00:28
	(b) (4)	

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '12:00'	Mariete Rendon (b) (4)	18 Aug 2020 20:00:28
	(b) (4)	

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '18 Aug 2020 12:00'	System	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '170.6' cm	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28
DataPoint set to visible.	System	18 Aug 2020 19:49:07

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '108.4' kg	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28
DataPoint set to visible.	System	18 Aug 2020 19:49:07

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
Amendment Manager: User entered '37.24528'	System	17 Sep 2020 00:12:44
User entered '37.2'	System	18 Aug 2020 20:00:28
DataPoint set to visible.	System	18 Aug 2020 19:49:07

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'kg/m2'	System	18 Aug 2020 20:00:28
DataPoint set to visible.	System	18 Aug 2020 19:49:07

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	18 Aug 2020 20:00:28
	(b) (4)	

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 11:10:54
Query 'Data is required. Please provide.' answered with 'per guidelines, ND' (Site from System).	Mariete Rendon (b) (4) (b) (4)	28 Aug 2020 21:33:01
User opened query 'Data is required. Please provide.' (Site from System).	System	18 Aug 2020 20:00:28
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 20:00:28
	(b) (4)	

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered missing code ND - Not Done.	Mariete Rendon (b) (4)	18 Aug 2020 20:00:28
	(b) (4)	

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'bpm'	System	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'breaths/min'	System	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mmHg'	System	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mmHg'	System	18 Aug 2020 20:00:28

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45

US3172185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45

US3172185

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 17:26:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:00:49

US3172185

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty; reason for change Data Entry Error	Jessie Downs (b) (4)	02 Oct 2020 17:26:07
	(b) (4)	
User entered '18 Aug 2020'	Mariete Rendon (b) (4)	18 Aug 2020 20:00:49
	(b) (4)	

US3172185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

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 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

US3172185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

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 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

US3172185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

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 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

US3172185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

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 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

US3172185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

[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 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

US3172185

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

[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 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

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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 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

Form: Risk of Exposure

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'CONSTRUCTION WORKER'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

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 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'I'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 19:59:24
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:31:03

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:59:24

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:45

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:45

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Clinic (Clinic)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:45

US3172185

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'VISIT1'	System	18 Aug 2020 20:08:45

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:09:24

US3172185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:23:47
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:23:47
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	18 Aug 2020 19:09:24
User entered '144236' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:09:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	18 Aug 2020 19:09:24

US3172185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

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)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

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)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:53

US3172185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:53

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Folder: Visit 1 Day 1

Form: Randomization

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[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:53

US3172185

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:31:03

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:08:53

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '12:00'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '18 Aug 2020 12:00'	System	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '36.5' C	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (Oral)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '81'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'bpm'	System	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '17'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'breaths/min'	System	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '133'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'mmHg'	System	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '80'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'mmHg'	System	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered missing code ND - Not Done.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 21:30:42
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Aug 2020 21:30:42
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Aug 2020 20:01:37
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '16:05' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 13:42:39
Amendment Manager: Query closed during migrationSystem process because the edit check no longer exists in target version.		21 Aug 2020 05:23:44
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		18 Aug 2020 21:30:42
User entered '16:12' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '18 Aug 2020 16:05'	System	21 Sep 2020 13:42:39
User entered '18 Aug 2020 16:12'	System	18 Aug 2020 21:30:42
User entered empty.	System	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '37.1' C reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '61' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'bpm'	System	18 Aug 2020 21:30:42
User entered empty.	System	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'breaths/min'	System	18 Aug 2020 21:30:42
User entered empty.	System	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '128' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 13:42:39
User entered '137' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'mmHg'	System	18 Aug 2020 21:30:42
User entered empty.	System	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	21 Sep 2020 13:42:39
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	21 Sep 2020 13:42:39
User entered '78' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Sep 2020 13:42:39
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:12:44
User entered '58' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 21:30:42
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'mmHg'	System	18 Aug 2020 21:30:42
User entered empty.	System	18 Aug 2020 20:01:37

US3172185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 17:26:22
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:33

US3172185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	02 Oct 2020 17:26:22
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:33

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'MRNA-1273 OR PLACEBO'	System	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '18 Aug 2020'	Mariete Rendon (b) (4)	18 Aug 2020 19:49:41
	(b) (4)	

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '15:42'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '18 Aug 2020 15:42'	System	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Right Arm (RIGHT ARM)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'ONCE'	System	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'INTRAMUSCULAR'	System	18 Aug 2020 19:49:41

US3172185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:44

US3172185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:44

US3172185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '15:34'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:44

US3172185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '18 Aug 2020 15:34'	System	18 Aug 2020 20:10:44

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '18 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '15:28'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '18 Aug 2020 15:28'	System	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:20:26
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4) (b) (4)	17 Sep 2020 13:20:26
User entered '15:28'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	17 Sep 2020 13:20:26
User entered '18 Aug 2020 15:28'	System	18 Aug 2020 20:10:58

US3172185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 19:12:27

US3172185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	26 Aug 2020 19:12:27

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:29:14', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4870dc17-9037-41af-9ffb-3503f3fa83c6'	System	18 Aug 2020 20:29:43
User entered 'Yes (Y)'	System	18 Aug 2020 20:29:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:29:25', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4870dc17-9037-41af-9ffb-3503f3fa83c6'	System	18 Aug 2020 20:29:43
User entered '98.8'	System	18 Aug 2020 20:29:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:29:34', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4870dc17-9037-41af-9ffb-3503f3fa83c6'	System	18 Aug 2020 20:29:43
User entered 'No (N)'	System	18 Aug 2020 20:29:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:29:40', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4870dc17-9037-41af-9ffb-3503f3fa83c6'	System	18 Aug 2020 20:29:43
User entered '18 Aug 2020 16:29'	System	18 Aug 2020 20:29:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 16:02'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 18:32'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:44:01', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '7f917d27-d8cc-43e7-8dcf-cd7e15ea8cdc'	System	18 Aug 2020 23:44:52
User entered 'Yes (Y)'	System	18 Aug 2020 23:44:52

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:44:21', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '7f917d27-d8cc-43e7-8dcf-cd7e15ea8cdc'	System	18 Aug 2020 23:44:52
User entered '98.6'	System	18 Aug 2020 23:44:52

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:44:30', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '7f917d27-d8cc-43e7-8dcf-cd7e15ea8cdc'	System	18 Aug 2020 23:44:52
User entered 'No (N)'	System	18 Aug 2020 23:44:52

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:44:49', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '7f917d27-d8cc-43e7-8dcf-cd7e15ea8cdc'	System	18 Aug 2020 23:44:52
User entered '18 Aug 2020 19:44'	System	18 Aug 2020 23:44:52

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 19:27'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 2'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:29:28', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'b68e5962-6242-43c9-815f-0616906fa0fa'	System	19 Aug 2020 21:30:09
User entered 'Yes (Y)'	System	19 Aug 2020 21:30:09

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:29:43', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'b68e5962-6242-43c9-815f-0616906fa0fa' User entered '97.7'	System	19 Aug 2020 21:30:09
	System	19 Aug 2020 21:30:09

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:29:51', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'b68e5962-6242-43c9-815f-0616906fa0fa'	System	19 Aug 2020 21:30:09
User entered 'No (N)'	System	19 Aug 2020 21:30:09

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:30:04', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'b68e5962-6242-43c9-815f-0616906fa0fa'	System	19 Aug 2020 21:30:09
User entered '19 Aug 2020 17:30'	System	19 Aug 2020 21:30:09

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 3'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:25:42', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f98b6df2-2aa9-4ccf-adda-3dfc01c51108'	System	20 Aug 2020 22:26:34
User entered 'Yes (Y)'	System	20 Aug 2020 22:26:34

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:25:57', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f98b6df2-2aa9-4ccf-adda-3dfc01c51108'	System	20 Aug 2020 22:26:34
User entered '97.5'	System	20 Aug 2020 22:26:34

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:26:15', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f98b6df2-2aa9-4ccf-adda-3dfc01c51108'	System	20 Aug 2020 22:26:34
User entered 'No (N)'	System	20 Aug 2020 22:26:34

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:26:27', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f98b6df2-2aa9-4ccf-adda-3dfc01c51108'	System	20 Aug 2020 22:26:34
User entered '20 Aug 2020 18:26'	System	20 Aug 2020 22:26:34

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 4'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:40:20', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'ec5df02a-e1a8-4419-aab6-fab85069c798'	System	21 Aug 2020 22:41:12
User entered 'Yes (Y)'	System	21 Aug 2020 22:41:12

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:40:51', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'ec5df02a-e1a8-4419-aab6-fab85069c798'	System	21 Aug 2020 22:41:12
User entered '97.8'	System	21 Aug 2020 22:41:12

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:40:58', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'ec5df02a-e1a8-4419-aab6-fab85069c798'	System	21 Aug 2020 22:41:12
User entered 'No (N)'	System	21 Aug 2020 22:41:12

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:41:09', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'ec5df02a-e1a8-4419-aab6-fab85069c798'	System	21 Aug 2020 22:41:12
User entered '21 Aug 2020 18:41'	System	21 Aug 2020 22:41:12

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 5'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T02:58:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '81ef7eaa-551b-48f1-b06d-bc6986a3619c'	System	23 Aug 2020 06:59:37
User entered 'Yes (Y)'	System	23 Aug 2020 06:59:37

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T02:58:18', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '81ef7eaa-551b-48f1-b06d-bc6986a3619c'	System	23 Aug 2020 06:59:37
User entered '97.6'	System	23 Aug 2020 06:59:37

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T02:59:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '81ef7eaa-551b-48f1-b06d-bc6986a3619c'	System	23 Aug 2020 06:59:37
User entered 'No (N)'	System	23 Aug 2020 06:59:37

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T02:59:33', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '81ef7eaa-551b-48f1-b06d-bc6986a3619c'	System	23 Aug 2020 06:59:37
User entered '23 Aug 2020 02:59'	System	23 Aug 2020 06:59:37

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 6'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:38:41', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '84266a01-b543-40cf-8c07-b4a0227d33bb'	System	23 Aug 2020 20:40:50
User entered 'Yes (Y)'	System	23 Aug 2020 20:40:50

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:40:25', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '84266a01-b543-40cf-8c07-b4a0227d33bb'	System	23 Aug 2020 20:40:50
User entered '97.5'	System	23 Aug 2020 20:40:50

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:40:34', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '84266a01-b543-40cf-8c07-b4a0227d33bb'	System	23 Aug 2020 20:40:50
User entered 'No (N)'	System	23 Aug 2020 20:40:50

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:40:46', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '84266a01-b543-40cf-8c07-b4a0227d33bb'	System	23 Aug 2020 20:40:50
User entered '23 Aug 2020 16:40'	System	23 Aug 2020 20:40:50

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 7'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:47:03', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '43f477ce-dda4-4d0d-b9e5-193926ee86ea'	System	24 Aug 2020 22:47:43
User entered 'Yes (Y)'	System	24 Aug 2020 22:47:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:47:15', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '43f477ce-dda4-4d0d-b9e5-193926ee86ea'	System	24 Aug 2020 22:47:43
User entered '97.5'	System	24 Aug 2020 22:47:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:47:23', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '43f477ce-dda4-4d0d-b9e5-193926ee86ea'	System	24 Aug 2020 22:47:43
User entered 'No (N)'	System	24 Aug 2020 22:47:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:47:37', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '43f477ce-dda4-4d0d-b9e5-193926ee86ea'	System	24 Aug 2020 22:47:43
User entered '24 Aug 2020 18:47'	System	24 Aug 2020 22:47:43

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:30:07', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '73b80acf-8418-451d-bca2-ec8d4d5b5db4'	System	18 Aug 2020 20:30:52
User entered 'None (1)'	System	18 Aug 2020 20:30:52

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:30:17', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '73b80acf-8418-451d-bca2-ec8d4d5b5db4'	System	18 Aug 2020 20:30:52
User entered 'No (N)'	System	18 Aug 2020 20:30:52

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:30:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '73b80acf-8418-451d-bca2-ec8d4d5b5db4'	System	18 Aug 2020 20:30:52
User entered 'No (N)'	System	18 Aug 2020 20:30:52

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:30:35', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '73b80acf-8418-451d-bca2-ec8d4d5b5db4'	System	18 Aug 2020 20:30:52
User entered 'None (1)'	System	18 Aug 2020 20:30:52

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:30:48', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '73b80acf-8418-451d-bca2-ec8d4d5b5db4'	System	18 Aug 2020 20:30:52
User entered '18 Aug 2020 16:30'	System	18 Aug 2020 20:30:52

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 16:02'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 18:32'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:45:44', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e237182-2d05-4f70-b526-a8013331705e'	System	18 Aug 2020 23:46:33
User entered 'None (1)'	System	18 Aug 2020 23:46:33

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:45:52', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e237182-2d05-4f70-b526-a8013331705e'	System	18 Aug 2020 23:46:33
User entered 'No (N)'	System	18 Aug 2020 23:46:33

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:46:02', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e237182-2d05-4f70-b526-a8013331705e'	System	18 Aug 2020 23:46:33
User entered 'No (N)'	System	18 Aug 2020 23:46:33

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:46:17', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e237182-2d05-4f70-b526-a8013331705e'	System	18 Aug 2020 23:46:33
User entered 'None (1)'	System	18 Aug 2020 23:46:33

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:46:29', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e237182-2d05-4f70-b526-a8013331705e'	System	18 Aug 2020 23:46:33
User entered '18 Aug 2020 19:46'	System	18 Aug 2020 23:46:33

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 19:27'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 2'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:30:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '476b097b-24a0-4723-a475-7402f922b63b'	System	19 Aug 2020 21:30:57
User entered 'Does not interfere with activity (2)'	System	19 Aug 2020 21:30:57

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:30:30', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '476b097b-24a0-4723-a475-7402f922b63b'	System	19 Aug 2020 21:30:57
User entered 'No (N)'	System	19 Aug 2020 21:30:57

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:30:35', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '476b097b-24a0-4723-a475-7402f922b63b'	System	19 Aug 2020 21:30:57
User entered 'No (N)'	System	19 Aug 2020 21:30:57

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:30:45', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '476b097b-24a0-4723-a475-7402f922b63b'	System	19 Aug 2020 21:30:57
User entered 'None (1)'	System	19 Aug 2020 21:30:57

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:30:52', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '476b097b-24a0-4723-a475-7402f922b63b'	System	19 Aug 2020 21:30:57
User entered '19 Aug 2020 17:30'	System	19 Aug 2020 21:30:57

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 3'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:26:42', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5972d2d5-dae1-403d-a21e-032538b1cdca'	System	20 Aug 2020 22:27:15
User entered 'None (1)'	System	20 Aug 2020 22:27:15

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:26:47', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5972d2d5-dae1-403d-a21e-032538b1cdca'	System	20 Aug 2020 22:27:15
User entered 'No (N)'	System	20 Aug 2020 22:27:15

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:26:54', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5972d2d5-dae1-403d-a21e-032538b1cdca'	System	20 Aug 2020 22:27:15
User entered 'No (N)'	System	20 Aug 2020 22:27:15

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:27:06', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5972d2d5-dae1-403d-a21e-032538b1cdca'	System	20 Aug 2020 22:27:15
User entered 'None (1)'	System	20 Aug 2020 22:27:15

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:27:10', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5972d2d5-dae1-403d-a21e-032538b1cdca'	System	20 Aug 2020 22:27:15
User entered '20 Aug 2020 18:27'	System	20 Aug 2020 22:27:15

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 4'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:41:23', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f2e49bb5-ac7f-4c2a-a0ee-46364593a8e6'	System	21 Aug 2020 22:42:06
User entered 'None (1)'	System	21 Aug 2020 22:42:06

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:41:30', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f2e49bb5-ac7f-4c2a-a0ee-46364593a8e6'	System	21 Aug 2020 22:42:06
User entered 'No (N)'	System	21 Aug 2020 22:42:06

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:41:35', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f2e49bb5-ac7f-4c2a-a0ee-46364593a8e6'	System	21 Aug 2020 22:42:06
User entered 'No (N)'	System	21 Aug 2020 22:42:06

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:41:56', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f2e49bb5-ac7f-4c2a-a0ee-46364593a8e6'	System	21 Aug 2020 22:42:06
User entered 'None (1)'	System	21 Aug 2020 22:42:06

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:01', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'f2e49bb5-ac7f-4c2a-a0ee-46364593a8e6'	System	21 Aug 2020 22:42:06
User entered '21 Aug 2020 18:42'	System	21 Aug 2020 22:42:06

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 5'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T02:59:52', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6fe846c6-aa13-40ab-8526-d1bd7c2a8a22'	System	23 Aug 2020 07:00:23
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 07:00:23

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:02', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6fe846c6-aa13-40ab-8526-d1bd7c2a8a22'	System	23 Aug 2020 07:00:23
User entered 'No (N)'	System	23 Aug 2020 07:00:23

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:08', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6fe846c6-aa13-40ab-8526-d1bd7c2a8a22'	System	23 Aug 2020 07:00:23
User entered 'No (N)'	System	23 Aug 2020 07:00:23

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:15', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6fe846c6-aa13-40ab-8526-d1bd7c2a8a22'	System	23 Aug 2020 07:00:23
User entered 'None (1)'	System	23 Aug 2020 07:00:23

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:20', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6fe846c6-aa13-40ab-8526-d1bd7c2a8a22'	System	23 Aug 2020 07:00:23
User entered '23 Aug 2020 03:00'	System	23 Aug 2020 07:00:23

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 6'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5062c6e1-6b7e-441e-9dc8-6d27593f2f3d'	System	23 Aug 2020 20:41:31
User entered 'None (1)'	System	23 Aug 2020 20:41:31

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:06', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5062c6e1-6b7e-441e-9dc8-6d27593f2f3d'	System	23 Aug 2020 20:41:31
User entered 'No (N)'	System	23 Aug 2020 20:41:31

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:18', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5062c6e1-6b7e-441e-9dc8-6d27593f2f3d'	System	23 Aug 2020 20:41:31
User entered 'No (N)'	System	23 Aug 2020 20:41:31

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5062c6e1-6b7e-441e-9dc8-6d27593f2f3d'	System	23 Aug 2020 20:41:31
User entered 'None (1)'	System	23 Aug 2020 20:41:31

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:28', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '5062c6e1-6b7e-441e-9dc8-6d27593f2f3d'	System	23 Aug 2020 20:41:31
User entered '23 Aug 2020 16:41'	System	23 Aug 2020 20:41:31

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 7'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:47:51', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '1600cc61-af28-4418-bedb-abd0238ae4bb'	System	24 Aug 2020 22:48:30
User entered 'None (1)'	System	24 Aug 2020 22:48:30

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:47:56', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '1600cc61-af28-4418-bedb-abd0238ae4bb'	System	24 Aug 2020 22:48:30
User entered 'No (N)'	System	24 Aug 2020 22:48:30

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:03', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '1600cc61-af28-4418-bedb-abd0238ae4bb'	System	24 Aug 2020 22:48:30
User entered 'No (N)'	System	24 Aug 2020 22:48:30

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:10', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '1600cc61-af28-4418-bedb-abd0238ae4bb'	System	24 Aug 2020 22:48:30
User entered 'None (1)'	System	24 Aug 2020 22:48:30

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '1600cc61-af28-4418-bedb-abd0238ae4bb'	System	24 Aug 2020 22:48:30
User entered '24 Aug 2020 18:48'	System	24 Aug 2020 22:48:30

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:30:57', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'None (0)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:01', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'None (0)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:06', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'None (0)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:14', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'None (0)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:19', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'None (0)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'None (0)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:38', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396'	System	18 Aug 2020 20:31:47
User entered 'No (N)'	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T16:31:44', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '9530a019-0610-488e-a607-5b8aa514c396' User entered '18 Aug 2020 16:31'	System	18 Aug 2020 20:31:47
	System	18 Aug 2020 20:31:47

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 16:02'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 18:32'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 1, after vaccination (at home)'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:46:50', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'None (0)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:46:55', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'None (0)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:47:03', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'None (0)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:47:10', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'None (0)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:47:16', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'None (0)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:47:21', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'None (0)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:47:36', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered 'No (N)'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-18T19:47:45', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'a33125e9-8474-4a8b-b88f-ad0947f5c922'	System	18 Aug 2020 23:47:49
User entered '18 Aug 2020 19:47'	System	18 Aug 2020 23:47:49

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '18 Aug 2020 19:27'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '19 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 2'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:02', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'None (0)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:06', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'None (0)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:12', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'None (0)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:19', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'None (0)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'None (0)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:27', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'None (0)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:44', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered 'No (N)'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-19T17:31:49', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '85f8b837-014d-4177-be02-dcf4ee1ae8a3'	System	19 Aug 2020 21:31:53
User entered '19 Aug 2020 17:31'	System	19 Aug 2020 21:31:53

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '19 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '20 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 3'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:27:36', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'None (0)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:27:45', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'None (0)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:27:53', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'None (0)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:27:59', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'None (0)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:28:04', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'None (0)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:28:08', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'None (0)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:28:14', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered 'No (N)'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-20T18:28:20', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6a9033f3-963b-4371-a3e3-6088c4bc6053'	System	20 Aug 2020 22:28:23
User entered '20 Aug 2020 18:28'	System	20 Aug 2020 22:28:23

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '20 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '21 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 4'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:14', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'None (0)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:18', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'None (0)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'None (0)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:29', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'None (0)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:36', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'None (0)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:41', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'None (0)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:47', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered 'No (N)'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-21T18:42:50', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'd0a386b3-e372-471f-a77b-19b42148ce75'	System	21 Aug 2020 22:42:54
User entered '21 Aug 2020 18:42'	System	21 Aug 2020 22:42:54

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '21 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '22 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 5'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:28', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'None (0)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:32', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'None (0)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:46', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'None (0)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:52', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'None (0)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:00:57', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'None (0)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:01:01', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'None (0)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:01:06', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered 'No (N)'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T03:01:10', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '000f150c-d2bc-456a-b83c-f6154c62f1fc'	System	23 Aug 2020 07:01:15
User entered '23 Aug 2020 03:01'	System	23 Aug 2020 07:01:15

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '22 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '23 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 6'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:39', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'None (0)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:50', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'None (0)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:41:56', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'None (0)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:42:11', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'None (0)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:42:16', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'None (0)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:42:20', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'None (0)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:42:25', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered 'No (N)'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-23T16:42:28', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '91da1f64-a1c5-4291-abe0-8a0bbd6e1274'	System	23 Aug 2020 20:42:34
User entered '23 Aug 2020 16:42'	System	23 Aug 2020 20:42:34

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '23 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '24 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 7'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:31', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb' User entered 'None (0)'	System	24 Aug 2020 22:49:16
	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:35', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb' User entered 'None (0)'	System	24 Aug 2020 22:49:16
	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:42', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb'	System	24 Aug 2020 22:49:16
User entered 'None (0)'	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:48', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb' User entered 'None (0)'	System	24 Aug 2020 22:49:16
	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:52', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb'	System	24 Aug 2020 22:49:16
User entered 'None (0)'	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:48:57', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb' User entered 'None (0)'	System	24 Aug 2020 22:49:16
	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

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 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:49:08', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb'	System	24 Aug 2020 22:49:16
User entered 'No (N)'	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-08-24T18:49:11', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: 'bc0db9d9-4970-4ca6-8483-b723e7bb18cb'	System	24 Aug 2020 22:49:16
User entered '24 Aug 2020 18:49'	System	24 Aug 2020 22:49:16

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '24 Aug 2020 12:00'	System	18 Aug 2020 19:49:41

US3172185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:31:03

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
User entered '25 Aug 2020 11:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 19:13:18

US3172185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '26 Aug 2020'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 19:13:18

US3172185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Contact Made (CONTACT MADE)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 19:13:18

US3172185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 19:13:18

US3172185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Aug 2020 19:13:22

US3172185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	26 Aug 2020 19:13:22

US3172185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 13:42:50

US3172185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '02 Sep 2020'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 13:42:50

US3172185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 13:42:50

US3172185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 13:42:50

US3172185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Sep 2020 13:42:54

US3172185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	03 Sep 2020 13:42:54

US3172185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 15:45:09

US3172185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '08 Sep 2020'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 15:45:09

US3172185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 15:45:09

US3172185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 15:45:09

US3172185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Sep 2020 15:45:13

US3172185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	10 Sep 2020 15:45:13

US3172185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	04 Nov 2020 07:37:58
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:09:44
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 14OCT2020 is reported under Visit 3 Day 57visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 11:04:46
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:10:59

US3172185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:10:59

US3172185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:10:59

US3172185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'VISIT2'	System	30 Sep 2020 20:10:59

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Pre-Dose (PREDOSE)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Post-Dose (POSTDOSE)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:03

US3172185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:07

US3172185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:07

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per CDM: Response note. "If No, reason not given recorded as Other". However in AE from log line 1 indicates "Action taken with investigational product is recorded as Investigational Product Withdrawn". Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:21:32
Query 'Per CDM: Response note. "If No, reason not given recorded as Other". However in AE from log line 1 indicates "Action taken with investigational product is recorded as Investigational Product Withdrawn". Please review and update the data else clarify. Thank you.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 19:35:26
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 19:34:33
User opened query 'Per CDM: Response note. "If No, reason not given recorded as Other". However in AE from log line 1 indicates "Action taken with investigational product is recorded as Investigational Product Withdrawn". Please review and update the data else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 03:37:18
User entered 'Other (OTHER)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Due to SAE Acute chest pressure' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	08 Oct 2020 19:34:33
User entered 'MISSED VISIT'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:20

US3172185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:24

US3172185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:24

US3172185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:11:24

US3172185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:11:24

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered empty.	System	30 Sep 2020 20:12:37

US3172185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:04:59
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	06 Oct 2020 20:56:26
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	30 Sep 2020 20:12:40

US3172185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '1'	System	03 Nov 2020 19:04:59
User entered empty.	System	06 Oct 2020 20:56:26
User entered '1'	System	30 Sep 2020 20:12:40

US3172185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:49:55

US3172185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '24 Sep 2020'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:49:55

US3172185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:49:55

US3172185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'unable to contact subject. left voicemail to call site back.'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:49:55

US3172185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:24

US3172185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	03 Nov 2020 19:05:24

US3172185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:42:19

US3172185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:53:23
	(b) (4)	
User entered '1 Oct 2020'	Mariete Rendon (b) (4)	26 Feb 2021 21:42:19
	(b) (4)	

US3172185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:42:19

US3172185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'unable to contact'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:42:19

US3172185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:32

US3172185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	03 Nov 2020 19:05:32

US3172185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:42:57

US3172185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4)	03 Mar 2021 13:53:23
	(b) (4)	
User entered '8 Oct 2020'	Mariete Rendon (b) (4)	26 Feb 2021 21:42:57
	(b) (4)	

US3172185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'Contact Not Made (CONTACT NOT MADE)'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:42:57

US3172185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'unable to contact'	Mariete Rendon (b) (4) (b) (4)	26 Feb 2021 21:42:57

US3172185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:37

US3172185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	03 Nov 2020 19:05:37

US3172185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:52

US3172185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '14 Oct 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:52

US3172185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:52

US3172185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'VISIT3'	System	03 Nov 2020 19:05:52

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '14 Oct 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '08:21'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '14 Oct 2020 08:21'	System	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '36.8' C	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '71'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'bpm'	System	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '16'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'breaths/min'	System	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '125'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'mmHg'	System	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '75'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'mmHg'	System	03 Nov 2020 19:07:09

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48

US3172185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48

US3172185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:06:25

US3172185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '14 Oct 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:06:25

US3172185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:06:14

US3172185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '14 Oct 2020'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:06:14

US3172185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '09:52'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:06:14

US3172185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered '14 Oct 2020 09:52'	System	03 Nov 2020 19:06:14

US3172185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	03 Nov 2020 19:05:56

US3172185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	03 Nov 2020 19:05:56

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 64'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '18 Oct 2020 00:01'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '22 Oct 2020 23:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 71'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-10-26T13:11:13', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '0d4e76c6-f93a-4b1c-a9a8-ebfbb3359822'	System	26 Oct 2020 17:12:15
User entered 'No (N)'	System	26 Oct 2020 17:12:15

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-10-26T13:11:20', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '0d4e76c6-f93a-4b1c-a9a8-ebfbb3359822'	System	26 Oct 2020 17:12:15
User entered 'No (N)'	System	26 Oct 2020 17:12:15

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2020-10-26T13:11:24', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '0d4e76c6-f93a-4b1c-a9a8-ebfbb3359822' User entered '26 Oct 2020 13:11:24'	System	26 Oct 2020 17:12:15
	System	26 Oct 2020 17:12:15

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '25 Oct 2020 00:01'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 12:06:02
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '29 Oct 2020 23:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 78'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '01 Nov 2020 00:01'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '05 Nov 2020 23:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered 'Day 92'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Please 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 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '15 Nov 2020 00:01'	System	18 Aug 2020 19:49:41

US3172185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 22:29:59
Data entry locked.	System	18 Aug 2020 19:49:41
User entered '19 Nov 2020 23:59'	System	18 Aug 2020 19:49:41

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 22:29:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 22:29:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 22:29:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 22:29:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 22:29:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-02-19T16:06:43', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '2b51d24c-3de9-46a6-9bfc-4c452f01e657'	System	19 Feb 2021 21:07:08
User entered 'No (N)'	System	19 Feb 2021 21:07:08

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-02-19T16:06:13', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '2b51d24c-3de9-46a6-9bfc-4c452f01e657'	System	19 Feb 2021 21:07:08
User entered 'No (N)'	System	19 Feb 2021 21:07:08

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-02-19T16:07:03', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '2b51d24c-3de9-46a6-9bfc-4c452f01e657'	System	19 Feb 2021 21:07:08
User entered '19 Feb 2021 16:07:03'	System	19 Feb 2021 21:07:08

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-03-08T18:10:36-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6303bf8f-74a3-4af5-a35e-09846644ca87'	System	08 Mar 2021 23:17:18
User entered 'No (N)'	System	08 Mar 2021 23:17:18

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-03-08T18:10:49-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6303bf8f-74a3-4af5-a35e-09846644ca87'	System	08 Mar 2021 23:17:18
User entered 'No (N)'	System	08 Mar 2021 23:17:18

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-03-08T18:11:21-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '6303bf8f-74a3-4af5-a35e-09846644ca87'	System	08 Mar 2021 23:17:18
User entered '08 Mar 2021 18:11:21'	System	08 Mar 2021 23:17:18

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-03-12T15:42:31-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '46cf80b7-315c-4630-b781-0cbe2c0c05b4'	System	12 Mar 2021 20:43:01
User entered 'No (N)'	System	12 Mar 2021 20:43:01

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-03-12T15:42:38-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '46cf80b7-315c-4630-b781-0cbe2c0c05b4'	System	12 Mar 2021 20:43:01
User entered 'No (N)'	System	12 Mar 2021 20:43:01

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-03-12T15:42:57-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '46cf80b7-315c-4630-b781-0cbe2c0c05b4' User entered '12 Mar 2021 15:42:57'	System	12 Mar 2021 20:43:01
	System	12 Mar 2021 20:43:01

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-03-22T18:49:35-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '57f31f1c-3211-4be3-99a3-858e450cd1e1'	System	22 Mar 2021 22:50:10
User entered 'No (N)'	System	22 Mar 2021 22:50:10

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-03-22T18:49:46-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '57f31f1c-3211-4be3-99a3-858e450cd1e1'	System	22 Mar 2021 22:50:10
User entered 'No (N)'	System	22 Mar 2021 22:50:10

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-03-22T18:50:07-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '57f31f1c-3211-4be3-99a3-858e450cd1e1' User entered '22 Mar 2021 18:50:07'	System	22 Mar 2021 22:50:10
	System	22 Mar 2021 22:50:10

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-03-29T19:10:19-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '80e316f0-a659-402e-8e46-9005e79d777c'	System	29 Mar 2021 23:12:10
User entered 'No (N)'	System	29 Mar 2021 23:12:10

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-03-29T19:10:39-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '80e316f0-a659-402e-8e46-9005e79d777c'	System	29 Mar 2021 23:12:10
User entered 'No (N)'	System	29 Mar 2021 23:12:10

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-03-29T19:11:01-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '80e316f0-a659-402e-8e46-9005e79d777c' User entered '29 Mar 2021 19:11:01'	System	29 Mar 2021 23:12:10
	System	29 Mar 2021 23:12:10

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-04-08T17:50:31-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e585c76-cc58-48fd-8a2d-51436032c9fd' User entered 'No (N)'	System	08 Apr 2021 21:50:47
	System	08 Apr 2021 21:50:47

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-04-08T17:50:37-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e585c76-cc58-48fd-8a2d-51436032c9fd'	System	08 Apr 2021 21:50:47
User entered 'No (N)'	System	08 Apr 2021 21:50:47

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-04-08T17:50:43-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '4e585c76-cc58-48fd-8a2d-51436032c9fd' User entered '08 Apr 2021 17:50:43'	System	08 Apr 2021 21:50:47
	System	08 Apr 2021 21:50:47

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-04-15T07:15:17-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '45ca05b3-e227-47bf-8ad1-94b8ed5b3a8e' User entered 'No (N)'	System	15 Apr 2021 11:15:51
	System	15 Apr 2021 11:15:51

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-04-15T07:15:35-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '45ca05b3-e227-47bf-8ad1-94b8ed5b3a8e'	System	15 Apr 2021 11:15:51
User entered 'No (N)'	System	15 Apr 2021 11:15:51

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-04-15T07:15:47-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '45ca05b3-e227-47bf-8ad1-94b8ed5b3a8e' User entered '15 Apr 2021 07:15:47'	System	15 Apr 2021 11:15:51
	System	15 Apr 2021 11:15:51

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[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 (8c09fe48dde3daa0)', Time: '2021-04-30T02:49:44-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '0e4e4e0d-b4db-4ea4-b03e-3ccfbb8d38b7'	System	30 Apr 2021 06:50:35
User entered 'No (N)'	System	30 Apr 2021 06:50:35

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

Have you been exposed to someone with 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 (8c09fe48dde3daa0)', Time: '2021-04-30T02:50:01-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '0e4e4e0d-b4db-4ea4-b03e-3ccfbb8d38b7'	System	30 Apr 2021 06:50:35
User entered 'No (N)'	System	30 Apr 2021 06:50:35

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-04-30T02:50:29-04:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '0e4e4e0d-b4db-4ea4-b03e-3ccfbb8d38b7'	System	30 Apr 2021 06:50:35
User entered '30 Apr 2021 02:50:29'	System	30 Apr 2021 06:50:35

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 22:29:59

US3172185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:31:03

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 22:29:59
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 22:29:59

US3172185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:03

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 12:31:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-03-03T18:09:28-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '78d84e62-3856-434c-bac7-41261c83b69e'	System	03 Mar 2021 23:14:28
User entered 'No (N)'	System	03 Mar 2021 23:14:28

US3172185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:31:03

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:31:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8c09fe48dde3daa0)', Time: '2021-03-03T18:09:46-05:00', User OID: 'PatientReportedOutcome (US3172185)', ODM File OID: '78d84e62-3856-434c-bac7-41261c83b69e'	System	03 Mar 2021 23:14:28
User entered '03 Mar 2021 18:09:46'	System	03 Mar 2021 23:14:28

US3172185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:40:43

US3172185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '12 Nov 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:41:33
User entered '12 Dec 2020'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:40:43

US3172185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:40:43

US3172185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:40:43

US3172185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	18 Dec 2020 20:40:53

US3172185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 07:09:48
User entered 'I'	System	18 Dec 2020 20:40:53

US3172185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:13:41

US3172185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:13:41

US3172185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered empty.	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:13:41

US3172185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	03 Mar 2021 13:53:23
User entered 'missed'	Jessie Downs (b) (4) (b) (4)	26 Feb 2021 20:13:41

US3172185

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Jan 2021 15:17:15

US3172185

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User entered 'I'	System	14 Jan 2021 15:17:15

US3172185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Jan 2021 15:18:06

US3172185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '13 Jan 2021'	Jessie Downs (b) (4) (b) (4)	14 Jan 2021 15:18:06

US3172185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4)	14 Jan 2021 15:18:06
	(b) (4)	

US3172185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	14 Jan 2021 15:18:06

US3172185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	14 Jan 2021 15:18:16

US3172185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User entered 'I'	System	14 Jan 2021 15:18:16

US3172185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 14:16:36
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Feb 2021 14:13:00

US3172185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 14:16:36
User entered '15 Feb 2021'	Jessie Downs (b) (4) (b) (4)	17 Feb 2021 14:13:00

US3172185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 14:16:36
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	17 Feb 2021 14:13:00

US3172185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 14:16:36
User entered empty.	Jessie Downs (b) (4) (b) (4)	17 Feb 2021 14:13:00

US3172185

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	17 Feb 2021 14:16:36
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	17 Feb 2021 14:12:36

US3172185

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	16 Apr 2021 13:54:02
User entered 'I'	System	17 Feb 2021 14:12:36

US3172185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:14

US3172185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:14

US3172185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:14

US3172185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	12 Apr 2021 18:56:14

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '08:52'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 08:52'	System	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '36.9' C	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '60'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '15'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '138'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '83'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:31:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 18:56:58

US3172185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:57:14

US3172185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:57:14

US3172185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 18:58:01

US3172185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 18:58:01

US3172185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '11:04'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:58:01

US3172185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 11:04'	System	12 Apr 2021 18:58:01

US3172185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:58:09

US3172185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered '1'	System	12 Apr 2021 18:58:09

US3172185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	13 Apr 2021 20:16:14

US3172185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '13 Apr 2021'	(b) (4), (b) (6) (b) (4)	13 Apr 2021 20:16:14

US3172185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Apr 2021 20:16:14

US3172185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6)	13 Apr 2021 20:16:14

US3172185

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	13 Apr 2021 20:16:42

US3172185

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 20:16:42

US3172185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	10 Mar 2021 22:48:17
	(b) (4)	

US3172185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '10 Mar 2021'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:48:17

US3172185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[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 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered 'Clinic (Clinic)'	Jessie Downs (b) (4)	10 Mar 2021 22:48:17
	(b) (4)	

US3172185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'UNBLND_DECIDE'	System	10 Mar 2021 22:48:17

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '06 Jan 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:48:49
	(b) (4)	

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	10 Mar 2021 22:48:49
	(b) (4)	

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	10 Mar 2021 22:48:49
	(b) (4)	

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User closed query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	15 Apr 2021 19:53:29
' (Site from DM). Query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	09 Apr 2021 22:59:40
' answered with 'Data updated ' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	09 Apr 2021 22:59:18
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Apr 2021 22:59:18
User opened query ' Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.	(b) (4), (b) (6)	09 Apr 2021 21:35:55
' (Site from DM). User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:48:49

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:48:49
	(b) (4)	

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4)	10 Mar 2021 22:48:49
	(b) (4)	

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:48:49

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Placebo (Placebo)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:48:49

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:48:49

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '1'	System	10 Mar 2021 22:48:49

US3172185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:31:03

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '1'	System	10 Mar 2021 22:48:49

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '115.8' kg	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	10 Mar 2021 22:51:08
DataPoint set to visible.	System	10 Mar 2021 22:48:49

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '115.8' kg	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	10 Mar 2021 22:51:08
DataPoint set to visible.	System	10 Mar 2021 22:48:49

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User accepted default value 'Pre-Dose (PREDOSE)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:51:08
	(b) (4)	

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '08:05'	Jessie Downs (b) (4)	10 Mar 2021 22:51:08
	(b) (4)	

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '10 Mar 2021 08:05'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '37.1' C	Jessie Downs (b) (4)	10 Mar 2021 22:51:08
	(b) (4)	

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '61'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'bpm'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '17'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'breaths/min'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '132'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mmHg'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '64'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mmHg'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered missing code ND - Not Done.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '115.8' kg	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:31:03

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered empty.	System	10 Mar 2021 22:51:08
DataPoint set to visible.	System	10 Mar 2021 22:48:49

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User accepted default value 'Post-Dose (POSTDOSE)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:51:08
	(b) (4)	

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '11:38'	Jessie Downs (b) (4)	10 Mar 2021 22:51:08
	(b) (4)	

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '10 Mar 2021 11:38'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '37.2' C	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Oral (Oral)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '60'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'bpm'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '17'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'breaths/min'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '110'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mmHg'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '80'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:51:08

US3172185

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mmHg'	System	10 Mar 2021 22:51:08

US3172185

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:52

US3172185

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

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:49:52
	(b) (4)	

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:40

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	10 Mar 2021 22:49:40
	(b) (4)	

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

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 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered empty.	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:40

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'mRNA-1273'	System	10 Mar 2021 22:49:40
DataPoint set to visible.	System	10 Mar 2021 22:48:49

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:49:40
	(b) (4)	

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '11:08'	Jessie Downs (b) (4)	10 Mar 2021 22:49:40
	(b) (4)	

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '10 Mar 2021 11:08'	System	10 Mar 2021 22:49:40

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered 'Right Arm (RIGHT ARM)'	Jessie Downs (b) (4)	10 Mar 2021 22:49:40
	(b) (4)	

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'ONCE'	System	10 Mar 2021 22:49:40

US3172185

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

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'INTRAMUSCULAR'	System	10 Mar 2021 22:49:40

US3172185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:06

US3172185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:49:06
	(b) (4)	

US3172185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '09:57'	Jessie Downs (b) (4)	10 Mar 2021 22:49:06
	(b) (4)	

US3172185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:31:03

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '10 Mar 2021 09:57'	System	10 Mar 2021 22:49:06

US3172185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:03

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:18

US3172185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:03

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4)	12 Mar 2021 20:13:04
	(b) (4)	
User entered '10 Mar 2021'	Jessie Downs (b) (4)	10 Mar 2021 22:49:18
	(b) (4)	

US3172185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:03

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered '09:58'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:18

US3172185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:31:03

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered '10 Mar 2021 09:58'	System	10 Mar 2021 22:49:18

US3172185

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

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	12 Mar 2021 20:13:04
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	10 Mar 2021 22:49:21

US3172185

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

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 08:20:45
User entered 'I'	System	10 Mar 2021 22:49:21

US3172185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:43:28

US3172185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '17 Mar 2021'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:43:28

US3172185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Contact Made (CONTACT MADE)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:43:28

US3172185

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:31:03

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:43:28

US3172185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	30 Mar 2021 18:43:32

US3172185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User entered 'I'	System	30 Mar 2021 18:43:32

US3172185

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:57:24
User entered 'I'	System	30 Mar 2021 18:43:32
DataPoint set to visible.	System	30 Mar 2021 18:43:32

US3172185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:58:52

US3172185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:58:52

US3172185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 18:58:52

US3172185

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:31:03

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	12 Apr 2021 18:58:52

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '08:52'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 08:52'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '36.9' C	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '60'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '15'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '138'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '83'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:31:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12:00'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 12:00'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '37.1' C	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '61'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '16'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '123'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '74'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:31:03

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	12 Apr 2021 19:00:24

US3172185

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	12 Apr 2021 19:00:37

US3172185

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:31:03

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:37

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6)	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	12 Apr 2021 19:00:58
DataPoint set to visible.	System	30 Mar 2021 18:43:32

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '12 Apr 2021'	(b) (4), (b) (6)	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '11:30'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '12 Apr 2021 11:30'	System	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

Which arm was used to give treatment?

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	12 Apr 2021 19:01:09
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	12 Apr 2021 19:01:09
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 19:01:09
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	12 Apr 2021 19:00:58
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:31:03

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	12 Apr 2021 19:00:58

US3172185

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	12 Apr 2021 19:01:19

US3172185

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:31:03

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	12 Apr 2021 19:01:19

US3172185

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:31:03

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:45:58
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:00:44
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	02 Sep 2020 16:32:48

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:56:43
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:32:52
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 17:32:46

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:49:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 20:16:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 20:16:37
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 20:16:05
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
	(b) (4), (b) (6)	
Data point term sent to Coder	System	12 Nov 2020 20:15:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
	(b) (4), (b) (6)	
User closed query 'PV Query: Event term was reported as non-cardiac chest pain. Please clarify the etiology/possible cause of the chest pain.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:25:25
	(b) (4), (b) (6)	
Query 'PV Query: Event term was reported as non-cardiac chest pain. Please clarify the etiology/possible cause of the chest pain.' answered with 'secondary to dyspnea on exertion and chest wall muscle exertional fatigue.' (Site from Safety).	Mariete Rendon (b) (4)	04 Nov 2020 20:08:34
	(b) (4)	
User opened query 'PV Query: Event term was reported as non-cardiac chest pain. Please clarify the etiology/possible cause of the chest pain.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:17:56
	(b) (4), (b) (6)	
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Non-cardiac chest pain, LLT: Non-cardiac chest pain - version MedDRA\\23.0.	Coder Import (b) (4)	21 Oct 2020 14:51:44
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0. Data point term sent to Coder Coding entries removed.	Coder Import (b) (4) (b) (4) System Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 14:51:44 21 Oct 2020 14:49:35 21 Oct 2020 14:49:31
User entered 'non cardiac CHEST PAIN' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 14:49:31
User closed query 'PV Query: Please provide the underlying cause of the acute chest pain symptom and consider updating the event term to the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:46:16
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: Acute chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:54:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0. Query 'PV Query: Please provide the underlying cause of the acute chest pain symptom and consider updating the event term to the final diagnosis.' answered with 'Data updated.' (Site from Safety).	Coder Import (b) (4) (b) (4) Jessie Downs (b) (4) (b) (4)	17 Oct 2020 09:54:08 16 Oct 2020 22:52:44
Data point term sent to Coder Coding entries removed.	System Jessie Downs (b) (4) (b) (4)	16 Oct 2020 22:52:38 16 Oct 2020 22:52:24
User entered 'ACUTE CHEST PAIN' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Oct 2020 22:52:24
User closed query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 11:56:20
User opened query 'PV Query: Please provide the underlying cause of the acute chest pain symptom and consider updating the event term to the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:47:24

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' answered with 'Awaiting on medical records from the hospital to determine if this AE is cardiac or non-cardiac related.' (Site from DM).	Jessie Downs (b) (4)	29 Sep 2020 20:30:45
User closed query 'PV Query: Please provide the underlying cause of the acute chest pain symptom and consider updating the event term to the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:17:15
User opened query 'Per DM CLR: Please specify if this is cardiac or non-cardiac related. If non-cardiac related, specify if Chest Pain is respiratory related pain, musculoskeletal and connective tissue related pain, or general pain and discomfort. Review and update Adverse Event condition as appropriate and ensure update is reconciled with any corresponding ConMed entries, if applicable.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 02:35:19
Query 'PV Query: Please provide the underlying cause of the acute chest pain symptom and consider updating the event term to the final diagnosis.' answered with 'Pending Medical records' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 17:47:16
User opened query 'PV Query: Please provide the underlying cause of the acute chest pain symptom and consider updating the event term to the final diagnosis.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 18:57:23
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest discomfort, LLT: Chest pressure - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 23:44:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Sep 2020 23:44:57
Data point term sent to Coder	System	14 Sep 2020 21:13:52
User entered 'Acute Chest Pressure'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:56:46
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:01:45
User entered 'No (N)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:56:48
User entered 'No (N)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:56:50
User entered 'No (N)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:56:55
User entered '7 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:01:45
	(b) (4)	
User entered '9 Sep 2020'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:00
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	14 Sep 2020 21:13:35
User entered empty; reason for change Data Entry Error	Mariete Rendon (b) (4)	14 Sep 2020 21:13:35
	(b) (4)	
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	14 Sep 2020 21:13:03
User entered '12:00'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	14 Sep 2020 21:13:35
User entered '9 Sep 2020 12:00'	System	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:02
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:01:45
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:03
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 12:20:59
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	21 Oct 2020 12:20:59
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Oct 2020 13:01:45
User entered '15 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:01:45
User entered empty.	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:05
User entered empty.	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
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).	(b) (4), (b) (6)	22 Oct 2020 17:48:49
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)	24 Sep 2020 18:53:04
User entered empty.	System	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:14:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User closed query 'PV Query: Since the subject was hospitalized for the event of acute chest pressure, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please explain.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 13:15:59
Query 'PV Query: Since the subject was hospitalized for the event of acute chest pressure, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please explain.' answered with 'Data was updated ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:31:28
User entered 'Grade 3/Severe (Grade 3/Severe)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 20:31:04
User opened query 'PV Query: Since the subject was hospitalized for the event of acute chest pressure, appropriate CTCAE grade should be grade 3 instead of grade 2. Please update the event severity as such. If the severity is to remain grade 2, please explain.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 18:52:30
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:12
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:16
User entered '0'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:18
User entered '0'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	22 Sep 2020 17:50:23
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject still in house at hospital. Pending records.' (Site from System).	Mariete Rendon (b) (4)	15 Sep 2020 19:56:02
	(b) (4)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	14 Sep 2020 21:13:03
User entered 'I'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:26
User closed query 'PV Query: Please confirm the hospital admission date for the SAES of non cardiac chest pain, acute exacerbation of systolic heart failure, and atrial fibrillation with rapid ventricular rate. The SAE forms states 07 Sep 2020 but the narrative for non cardiac chest pain states 10 Sep 2020' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:25:34
Query 'PV Query: Please confirm the hospital admission date for the SAES of non cardiac chest pain, acute exacerbation of systolic heart failure, and atrial fibrillation with rapid ventricular rate. The SAE forms states 07 Sep 2020 but the narrative for non cardiac chest pain states 10 Sep 2020' answered with 'Data correct as is. Narrative updated to state 07SEP2020.' (Site from Safety).	Mariete Rendon (b) (4)	04 Nov 2020 20:10:27
	(b) (4)	
User opened query 'PV Query: Please confirm the hospital admission date for the SAES of non cardiac chest pain, acute exacerbation of systolic heart failure, and atrial fibrillation with rapid ventricular rate. The SAE forms states 07 Sep 2020 but the narrative for non cardiac chest pain states 10 Sep 2020' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:17:41
User entered '07 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Oct 2020 22:54:16
	(b) (4)	
User entered '10 Sep 2020'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:28
User closed query 'PV Query: Please confirm the hospital discharge date for the SAES of non cardiac chest pain, acute exacerbation of systolic heart failure, and atrial fibrillation with rapid ventricular rate. The discharge date for non cardiac chest pain was 15 Sep 2020 and the other events were 16 Sep 2020. Please clarify and amend.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:25:41
Query 'PV Query: Please confirm the hospital discharge date for the SAES of non cardiac chest pain, acute exacerbation of systolic heart failure, and atrial fibrillation with rapid ventricular rate. The discharge date for non cardiac chest pain was 15 Sep 2020 and the other events were 16 Sep 2020. Please clarify and amend.' answered with 'All the SAE's resolved by 15SEP2020 when the subject was discharged.' (Site from Safety).	Mariete Rendon (b) (4)	04 Nov 2020 20:11:26
	(b) (4)	
User opened query 'PV Query: Please confirm the hospital discharge date for the SAES of non cardiac chest pain, acute exacerbation of systolic heart failure, and atrial fibrillation with rapid ventricular rate. The discharge date for non cardiac chest pain was 15 Sep 2020 and the other events were 16 Sep 2020. Please clarify and amend.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 16:16:51
User closed query 'PV Query: Please provide hospital discharge date.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 15:46:22

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'PV Query: Please provide hospital discharge date.' answered with 'Data updated' (Site from Safety).	Jessie Downs (b) (4)	16 Oct 2020 22:54:28
User entered '15 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Oct 2020 22:54:16
User opened query 'PV Query: Please provide hospital discharge date.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:46:53
User closed query 'PV Query: Please provide hospital discharge date.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:17:24
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:17:21
Query 'PV Query: Please provide hospital discharge date.' answered with 'Pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 18:28:42
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Pending Medical Records' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 18:28:29
User opened query 'PV Query: Please provide hospital discharge date.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 18:56:07
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)	24 Sep 2020 18:52:46
User entered empty.	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:31
User entered 'No (N)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:34
User entered empty.	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:35
User entered '0'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:37
User entered '0'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:39
User entered '0'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:50:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:42
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:41
Query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	25 Sep 2020 13:14:41
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 21:13:03
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:50:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:46
User closed query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:21:41
Query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' answered with 'dosing Discontinuation updated' (Site from DM).	Mariete Rendon (b) (4)	28 Sep 2020 15:50:54
	(b) (4)	
User opened query 'Per CDM: "Action taken with investigational product is Investigational Product Withdrawn". However Exposure form in Visit2 Day 29 and Dosing Discontinuation form is not updated under End of study folder. Please review and update else clarify. Thank you' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:37:18
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:03:00
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:51
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:57:49
User entered '1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	04 Nov 2020 20:12:40
User entered '0'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:58:00
User closed query 'Per DM CLR: RQ: Response noted, however, there is no medication with this AE term as indication. Please update the medication's indication to include this AE as appropriate. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:56:42
Query 'Per DM CLR: RQ: Response noted, however, there is no medication with this AE term as indication. Please update the medication's indication to include this AE as appropriate. Otherwise, clarify in query response.' answered with 'Data updated.' (Site from DM).	Mariete Rendon (b) (4)	04 Nov 2020 20:12:54
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4)	04 Nov 2020 20:12:40
	(b) (4)	
User opened query 'Per DM CLR: RQ: Response noted, however, there is no medication with this AE term as indication. Please update the medication's indication to include this AE as appropriate. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:43:15
User closed query 'Per DM CLR RQ: Please keep query open until records have been obtained and Con Med eCRF has been updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:43:15

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR RQ: Please keep query open until records have been obtained and Con Med eCRF has been updated. Thank you.' answered with 'Conmeds updated' (Site from DM).	Mariete Rendon (b) (4)	22 Oct 2020 22:33:47
User opened query 'Per DM CLR RQ: Please keep query open until records have been obtained and Con Med eCRF has been updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:23:49
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	10 Oct 2020 12:23:49
' (Site from DM).		
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	Jessie Downs (b) (4)	29 Sep 2020 21:40:53
' answered with 'Awaiting on Medical Records ' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.	(b) (4), (b) (6)	29 Sep 2020 02:34:59
' (Site from DM).		
User entered 'I'	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:58:06
User closed query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are not therapeutic. Please review response and add any therapeutic procedures as appropriate. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:56:53
Query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are not therapeutic. Please review response and add any therapeutic procedures as appropriate. Otherwise, clarify in query response.' answered with 'Data updated' (Site from DM).	Mariete Rendon (b) (4)	04 Nov 2020 20:13:00
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Mariete Rendon (b) (4)	04 Nov 2020 20:12:40
	(b) (4)	
User opened query 'Per DM CLR: RQ: Response noted, however, the recorded procedures are not therapeutic. Please review response and add any therapeutic procedures as appropriate. Otherwise, clarify in query response.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:41:19
User closed query 'Per DM CLR RQ: Please keep query open until records have been obtained and Con Procedure eCRF has been updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 13:41:19
Query 'Per DM CLR RQ: Please keep query open until records have been obtained and Con Procedure eCRF has been updated. Thank you.' answered with 'See Conmed procedure page.' (Site from DM).	Mariete Rendon (b) (4)	21 Oct 2020 12:24:20
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR RQ: Please keep query open until records have been obtained and Con Procedure eCRF has been updated. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:24:23
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Oct 2020 12:24:23
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Waiting on Medical Records ' (Site from DM).	Jessie Downs (b) (4) (b) (4)	29 Sep 2020 21:41:06
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 02:34:57
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:58:14
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).	(b) (4), (b) (6)	21 Oct 2020 13:47:13
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 'Data updated' (Site from Safety).	Mariete Rendon (b) (4)	21 Oct 2020 12:24:43
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	21 Oct 2020 12:20:59
Data Entry Error		
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).	(b) (4), (b) (6)	07 Oct 2020 19:46:34
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).	(b) (4), (b) (6)	29 Sep 2020 13:17:29

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[Outcome](#)

Audit	User	Time (GMT)
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 'pending medical records.' (Site from Safety).	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 18:28:58
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).	(b) (4), (b) (6) (b) (4)	24 Sep 2020 18:54:07
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:13:03

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:58:16
User entered empty.	Mariete Rendon (b) (4)	14 Sep 2020 21:13:03
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:58:18

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ACUTE CHEST PRESSURE ASSOCIATED WITH TO DYSPNEA ON EXERTION AND FATIGUE STARTING ON 09SEP2020. SUBJECT WENT TO ER ON 07SEP2020 WHERE HE WAS ADMITTED. STILL IN HOUSE. HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). INFORMATION GATHERED BY PHONE DIRECTLY FROM SUBJECT. WILL REQUEST HOSPITALIZATION RECORDS WHEN SUBJECT IS DISCHARGED HOME. HE IS RECOVERING. THE EVENT MEET SAE CRITERIA AND DETAILS RELATED TO THE EVENT WILL BE PROVIDED WHEN MR'S ARE AVAILABLE. SUBJECT HAD TRANSESESOPHAGEAL ECHOCARDIOGRAM ON 11SEP2020 (NO EGD) FINDINGS: ARE SUGGESTIVE OF PROSTHETIC MITRAL VALVE STENOSIS. TRACE PULMONIC VALVULAR REGURGITATION. THERE IS TRACE TRICUSPID REGURGITATION. MILD ATHEROSCLEROTIC PLAQUE(S) IN THE DESCENDING AORTA.BIOPROSTHETIC MITRAL VALVE STENOSIS. CARDIAC CATHETERIZATION DONE ON 14SEP2020 FINDINGS: 1. MILD MITRAL VALVE STENOSIS, GRADIENT ACROSS THE MITRAL VALVE OF ONLY 4MMHG, CALCULATED MITRAL VALVE AREA 2.17 SQ CM. THIS REPRESENTS NORMAL HEMODYNAMICS FOR THIS BIOPROSTHETIC VALVE. 2. NO EVIDENCE OF OBSTRUCTIVE CORONARY ARTERY DISEASE. 3.NORMAL CARDIAC OUTPUT AND CARDIAC INDEX. 4.NORMAL RIGHT-SIDED CARDIAC PRESSURE. ADULT ECHO DONE ON 09SEP2020, FINDINGS: LEFT VENTRICULAR SYSTOLIC FUNCTION IS MILD TO MODERATELY REDUCED. THE RIGHT VENTRICULAR SYSTOLIC FUNCTION IS MILD TO MODERATELY REDUCED. MILD TO	Mariete Rendon (b) (4)	04 Nov 2020 20:10:04

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
MODERATE VALVULAR AORTIC STENOSIS. GRADIENT ARE ABNORMAL FOR THIS PROTHETIC MITRAL VALVE. LAB DONE ON 07SEP2020: PH 7.44, HCF03 32MMOL/L, BASE EXCESS 8MMOL/L, HGB 02 SAT VEN 77.0%, APTT 41 SECONDS, POTASSIUM 3.2MMOL/L, TOTAL CO2 CONTENT 40MMOL/L, ANION GAP <2, NT-PROBNP 3,410.0 PG/ML, HEMOGLOBIN 9.0 G/DL, HEMATOCRIT 31.2%, MCH 25.9 PG, MCHC 28.8 G/DL, RDW-CV 17.5%. LAB DONE ON 14SEP2020: HEMOGLOBIN 11.8 G/DL RANGE: 13.3-16.3, HEMATOCRIT 38.9% RANGE: 39.0-47.1' reason for change: Data Entry Error		
User closed query 'Per DM CLR: SAE Narrative = HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 18:11:15
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 15:14:13
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 13:25:00
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).	(b) (4), (b) (6)	23 Oct 2020 13:24:50
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'Labs added to narrative' (Site from Safety).	Mariete Rendon (b) (4)	23 Oct 2020 12:55:38
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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ACUTE CHEST PRESSURE ASSOCIATED WITH TO DYSPNEA ON EXERTION AND FATIGUE STARTING ON 09SEP2020. SUBJECT WENT TO ER ON 10SEP2020 WHERE HE WAS ADMITTED. STILL IN HOUSE. HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). INFORMATION GATHERED BY PHONE DIRECTLY FROM SUBJECT. WILL REQUEST HOSPITALIZATION RECORDS WHEN SUBJECT IS DISCHARGED HOME. HE IS RECOVERING. THE EVENT MEET SAE CRITERIA AND DETAILS RELATED TO THE EVENT WILL BE PROVIDED WHEN MR'S ARE AVAILABLE. SUBJECT HAD TRANSESESOPHAGEAL ECHOCARDIOGRAM ON 11SEP2020 (NO EGD) FINDINGS: ARE SUGGESTIVE OF PROSTHETIC MITRAL VALVE STENOSIS. TRACE PULMONIC VALVULAR REGURGITATION. THERE IS TRACE TRICUSPID REGURGITATION. MILD ATHEROSCLEROTIC PLAQUE(S) IN THE DESCENDING AORTA.BIOPROSTHETIC MITRAL VALVE STENOSIS. CARDIAC CATHETERIZATION DONE ON 14SEP2020 FINDINGS: 1. MILD MITRAL VALVE STENOSIS, GRADIENT ACROSS THE MITRAL VALVE OF ONLY 4MMHG, CALCULATED MITRAL VALVE AREA 2.17 SQ CM. THIS REPRESENTS NORMAL HEMODYNAMICS FOR THIS BIOPROSTHETIC VALVE. 2. NO EVIDENCE OF OBSTRUCTIVE CORONARY ARTERY DISEASE. 3.NORMAL CARDIAC OUTPUT AND CARDIAC INDEX. 4.NORMAL RIGHT-SIDED CARDIAC PRESSURE. ADULT ECHO DONE ON 09SEP2020, FINDINGS: LEFT VENTRICULAR SYSTOLIC FUNCTION IS MILD TO MODERATELY REDUCED. THE RIGHT VENTRICULAR SYSTOLIC FUNCTION IS MILD TO MODERATELY REDUCED. MILD TO	Mariete Rendon (b) (4)	23 Oct 2020 12:55:16

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
MODERATE VALVULAR AORTIC STENOSIS. GRADIENT ARE ABNORMAL FOR THIS PROTHETIC MITRAL VALVE. Lab done on 07SEP2020: PH 7.44, HCF03 32mmol/L, base excess 8mmol/L, Hgb 02 sat ven 77.0%, aptt 41 seconds, potassium 3.2mmol/L, Total CO2 content 40mmol/L, anion Gap <2, NT-proBNP 3,410.0 pg/ml, hemoglobin 9.0 g/dl, hematocrit 31.2%, MCH 25.9 pg, mchc 28.8 g/dl, rdw-cv 17.5%. Lab done on 14SEP2020: Hemoglobin 11.8 g/dl Range: 13.3-16.3, Hematocrit 38.9% Range: 39.0-47.1' reason for change: Data Entry Error		
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 testing located in medical records at admission.' (Site from Safety).	Mariete Rendon (b) (4)	22 Oct 2020 22:34:37
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 'conmed updated' (Site from Safety).	Mariete Rendon (b) (4)	22 Oct 2020 22:33:56
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)	22 Oct 2020 13:22:53
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 'Hospital discharge summary will send to Safety_Moderna@iqvia.com or fax to 866.599.1342 today 21OCT2020 with redacted information and subject #.' (Site from Safety).	Mariete Rendon (b) (4)	21 Oct 2020 15:17:58

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Per source document subject underwent EGD and a cardiac catheterization. Please provide results when available.' (Site from Safety).	(b) (4), (b) (6)	21 Oct 2020 13:47:24

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User entered 'ACUTE CHEST PRESSURE ASSOCIATED WITH TO DYSPNEA ON EXERTION AND FATIGUE STARTING ON 09SEP2020. SUBJECT WENT TO ER ON 10SEP2020 WHERE HE WAS ADMITTED. STILL IN HOUSE. HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). INFORMATION GATHERED BY PHONE DIRECTLY FROM SUBJECT. WILL REQUEST HOSPITALIZATION RECORDS WHEN SUBJECT IS DISCHARGED HOME. HE IS RECOVERING. THE EVENT MEET SAE CRITERIA AND DETAILS RELATED TO THE EVENT WILL BE PROVIDED WHEN MR'S ARE AVAILABLE. SUBJECT HAD TRANSESESOPHAGEAL ECHOCARDIOGRAM ON 11SEP2020 (NO EGD) FINDINGS: ARE SUGGESTIVE OF PROSTHETIC MITRAL VALVE STENOSIS. TRACE PULMONIC VALVULAR REGURGITATION. THERE IS TRACE TRICUSPID REGURGITATION. MILD ATHEROSCLEROTIC PLAQUE(S) IN THE DESCENDING AORTA.BIOPROSTHETIC MITRAL VALVE STENOSIS. CARDIAC CATHETERIZATION DONE ON 14SEP2020 FINDINGS: 1. MILD MITRAL VALVE STENOSIS, GRADIENT ACROSS THE MITRAL VALVE OF ONLY 4MMHG, CALCULATED MITRAL VALVE AREA 2.17 SQ CM. THIS REPRESENTS NORMAL HEMODYNAMICS FOR THIS BIOPROSTHETIC VALVE. 2. NO EVIDENCE OF OBSTRUCTIVE CORONARY ARTERY DISEASE. 3.NORMAL CARDIAC OUTPUT AND CARDIAC INDEX. 4.NORMAL RIGHT-SIDED CARDIAC PRESSURE. Adult Echo done on 09SEP2020, Findings: Left ventricular systolic function is mild to moderately reduced. the right ventricular systolic function is mild to moderately reduced. mild to moderate valvular aortic staenosis. Gradient are abnormal for this prothetic mitral valve.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 13:15:59

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per source document subject underwent EGD and a cardiac catheterization. Please provide results when available.' answered with 'Results Results/findings added to narrative.' (Site from Safety).	Mariete Rendon (b) (4)	21 Oct 2020 12:52:22
User entered 'ACUTE CHEST PRESSURE ASSOCIATED WITH TO DYSPNEA ON EXERTION AND FATIGUE STARTING ON 09SEP2020. SUBJECT WENT TO ER ON 10SEP2020 WHERE HE WAS ADMITTED. STILL IN HOUSE. HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). INFORMATION GATHERED BY PHONE DIRECTLY FROM SUBJECT. WILL REQUEST HOSPITALIZATION RECORDS WHEN SUBJECT IS DISCHARGED HOME. HE IS RECOVERING. THE EVENT MEET SAE CRITERIA AND DETAILS RELATED TO THE EVENT WILL BE PROVIDED WHEN MR'S ARE AVAILABLE. SUBJECT HAD TRANSESESOPHAGEAL ECHOCARDIOGRAM ON 11SEP2020 (NO EGD) Findings: are suggestive of prosthetic mitral valve stenosis. Trace pulmonic valvular regurgitation. There is trace tricuspid regurgitation. mild atherosclerotic plaque(s) in the descending aorta.bioprothetic mitral valve stenosis. CARDIAC CATHETERIZATION DONE ON 14SEP2020 Findings: 1. mild mitral valve stenosis, gradient across the mitral valve of only 4mmHg, calculated mitral valve area 2.17 sq cm. this represents normal hemodynamics for this bioprothetic valve. 2. no evidence of obstructive coronary artery disease. 3.normal cardiac output and cardiac index. 4.normal right-sided cardiac pressure.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 12:51:38

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'See Conmed procedure page.' (Site from DM).	Mariete Rendon (b) (4)	21 Oct 2020 12:25:14
User entered 'ACUTE CHEST PRESSURE ASSOCIATED WITH TO DYSPNEA ON EXERTION AND FATIGUE STARTING ON 09SEP2020. SUBJECT WENT TO ER ON 10SEP2020 WHERE HE WAS ADMITTED. STILL IN HOUSE. HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). INFORMATION GATHERED BY PHONE DIRECTLY FROM SUBJECT. WILL REQUEST HOSPITALIZATION RECORDS WHEN SUBJECT IS DISCHARGED HOME. HE IS RECOVERING. THE EVENT MEET SAE CRITERIA AND DETAILS RELATED TO THE EVENT WILL BE PROVIDED WHEN MR'S ARE AVAILABLE. Subject had Transesophageal echocardiogram on 11SEP2020 (NO EGD). Cardiac catheterization done on 14SEP2020.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:01:45
User opened query 'Per DM CLR: SAE Narrative = HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	13 Oct 2020 03:50:43
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:47:05

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	07 Oct 2020 19:46:42
User opened query 'PV Query: Per source document subject underwent EGD and a cardiac catheterization. Please provide results when available.' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:46:24
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	07 Oct 2020 19:46:16
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)	07 Oct 2020 19:45:41
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:17:35
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).	(b) (4), (b) (6)	29 Sep 2020 13:17:34
User closed query 'PV Query: Per source document subject underwent EGD and a cardiac catheterization. Please provide results when available.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:17:32

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Sep 2020 13:17:31
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 18:29:20
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 'pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 18:29:16
Query 'PV Query: Per source document subject underwent EGD and a cardiac catheterization. Please provide results when available.' answered with 'pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 18:29:12
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records.' (Site from Safety).	Mariete Rendon (b) (4)	28 Sep 2020 18:29:05
User entered 'ACUTE CHEST PRESSURE ASSOCIATED WITH TO DYSPNEA ON EXERTION AND FATIGUE STARTING ON 09SEP2020. SUBJECT WENT TO ER ON 10SEP2020 WHERE HE WAS ADMITTED. STILL IN HOUSE. HE UNDERWENT AN EGD TO RULE OUT GI CAUSES AND A CARDIAC CATHETER TODAY TO RULE OUT CV CAUSES (OTHERS). INFORMATION GATHERED BY PHONE DIRECTLY FROM SUBJECT. WILL REQUEST HOSPITALIZATION RECORDS WHEN SUBJECT IS DISCHARGED HOME. HE IS RECOVERING. THE EVENT MEET SAE CRITERIA AND DETAILS RELATED TO THE EVENT WILL BE PROVIDED WHEN MR'S ARE Available.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	28 Sep 2020 15:53:13

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
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)	24 Sep 2020 18:56:27
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).	(b) (4), (b) (6)	24 Sep 2020 18:55:51
User opened query 'PV Query: Per source document subject underwent EGD and a cardiac catheterization. Please provide results when available.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 18:53:42
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	24 Sep 2020 18:53:28
User entered 'acute chest pressure associated with to dyspnea on exertion and fatigue starting on 09SEP2020. Subject went to ER on 10SEP2020 where he was admitted. still in house. he underwent an EGD to rule out GI causes and a cardiac catheter today to rule out CV causes (others). information gathered by phone directly from subject. Will request hospitalization records when subject is discharged home. he is recovering. The event meet SAE criteria and details related to the event will be provided when MR's are available.'	Mariete Rendon (b) (4) (b) (4)	14 Sep 2020 21:13:03

US3172185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'I'	System	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '1'	System	20 Oct 2020 13:01:45
User entered '0'	System	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:31:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	System	14 Sep 2020 21:13:03

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:37
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:48:34
User entered	(b) (4), (b) (6)	21 Oct 2020 13:48:20
'USA-US118-2020-mRNA-1273-P301000003'		

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Acute left ventricular failure, LLT: Acute systolic heart failure - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 20:16:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	12 Nov 2020 20:16:38
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	System	12 Nov 2020 20:16:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
Data point term sent to Coder	System	12 Nov 2020 20:15:03
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:38
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Acute left ventricular failure, LLT: Acute systolic heart failure - version MedDRA\23.0.	Coder Import (b) (4)	21 Oct 2020 23:14:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	21 Oct 2020 23:14:43
Coding entries removed.	System	21 Oct 2020 14:50:36
	Mariete Rendon (b) (4)	21 Oct 2020 14:50:17
	(b) (4)	
User entered 'ACUTE exacerbation of systolic HEART FAILURE' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 14:50:17
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure acute, LLT: Acute heart failure - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 13:05:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	20 Oct 2020 13:05:33
	(b) (4)	
	System	20 Oct 2020 13:04:31

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Acute heart failure'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:03:40

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:42
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:46
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:47
User entered '7 Sep 2020'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:49
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	20 Oct 2020 13:03:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:04:51
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:26:48
User closed query 'Should this be 15Sep2020?' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:26:45
Query 'Should this be 15Sep2020?' answered with 'Source verified. Date was corrected.' (Site from CRA).	Jessie Downs (b) (4)	13 Nov 2020 15:56:15
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 15:55:51
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User opened query 'Should this be 15Sep2020?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:05:19
User entered '16 Sep 2020'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:24
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	20 Oct 2020 13:03:40

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:51:06
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:27
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:29
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:31
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:32
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		20 Oct 2020 13:18:48
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 by data change (Site from System).		20 Oct 2020 13:18:48
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	20 Oct 2020 13:03:40
User entered 'I'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:05:35
User entered '7 Sep 2020'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Should this be 15Sep2020?' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:27:00
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:26:58
Query 'Should this be 15Sep2020?' answered with 'Source verified. Date was corrected.' (Site from CRA).	Jessie Downs (b) (4)	13 Nov 2020 15:56:20
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 15:55:51
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User opened query 'Should this be 15Sep2020?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:05:59
User entered '16 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:17:00
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:05
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:18:48
User entered empty.	(b) (4)	
	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:08
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:10
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:12
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:13
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:51:13
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:51:15
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:19
User entered 'None (NONE)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:22
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:24
User entered 'I'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:25
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:30
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40
	(b) (4)	

US3172185

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'PV Query: Exclusion criteria includes Known history of SARS-CoV-2 infection. Please consider whether these event should be deleted.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 23:03:07
User closed query 'PV Query: Were the reported events considered as a manifestation of another disease which could cause heart strain, such as lung disorders? If not, please state so and provide imaging diagnosis of the lung?' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 23:03:04
Query 'PV Query: Exclusion criteria includes Known history of SARS-CoV-2 infection. Please consider whether these event should be deleted.' answered with 'No, deletion. Subject didn't disclose SARS-COV2 infection history at the time of screening being considered a deviation.' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:43:55
Query 'PV Query: Were the reported events considered as a manifestation of another disease which could cause heart strain, such as lung disorders? If not, please state so and provide imaging diagnosis of the lung?' answered with 'secondary to rapid ventricular response atrial fibrillation and mitral valve restenosis. ' (Site from Safety).	Jessie Downs (b) (4) (b) (4)	24 Nov 2020 21:42:26
User opened query 'PV Query: Exclusion criteria includes Known history of SARS-CoV-2 infection. Please consider whether these event should be deleted.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 17:22:11
User opened query 'PV Query: Were the reported events considered as a manifestation of another disease which could cause heart strain, such as lung disorders? If not, please state so and provide imaging diagnosis of the lung?' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 17:20:51
User closed query 'PV query: Please clarify why this subject was enrolled in this study. Exclusion criteria includes Known history of SARS-CoV-2 infection. ' (Site from Safety).	(b) (4), (b) (6)	18 Nov 2020 15:12:26

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV query: Please clarify why this subject was enrolled in this study. Exclusion criteria includes Known history of SARS-CoV-2 infection. ' answered with 'Subject did not disclose any significant medical history at screening visit.' (Site from Safety).	Jessie Downs (b) (4)	17 Nov 2020 17:59:29
User opened query 'PV query: Please clarify why this subject was enrolled in this study. Exclusion criteria includes Known history of SARS-CoV-2 infection. ' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 20:40:38
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:06:31
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 13:17:00
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Oct 2020 13:17:00
User entered 'subject of history of chronic heart failure with several episodes of exacerbation in the last 2 years secondary to mitral valve replacement with prosthetic replacement in 2017 and restenosis since last year.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:17:00
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 13:03:40
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:03:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'I'	System	20 Oct 2020 13:03:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'I'	System	20 Oct 2020 13:03:40

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 15:31:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	System	20 Oct 2020 13:18:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:01
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:49:37
User entered	(b) (4), (b) (6)	21 Oct 2020 13:49:33
'USA-US118-2020-mRNA-1273-P301000003'		

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation with rapid ventricular response - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 20:31:34
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 20:31:34
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation with rapid ventricular response - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 20:16:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	12 Nov 2020 20:16:40
	(b) (4)	
Data point term sent to Coder	System	12 Nov 2020 20:16:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
	(b) (4), (b) (6)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
	(b) (4), (b) (6)	
Data point term sent to Coder	System	12 Nov 2020 20:15:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:03
	(b) (4), (b) (6)	
User coded data point as SOC: Cardiac disorders, HLGT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation with rapid ventricular response - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 07:24:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 07:24:37
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 14:58:53
Coding entries removed.	Mariete Rendon (b) (4)	21 Oct 2020 14:58:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'ATRIAL FIBRILATION with rapid ventricular rate' reason for change: Data Entry Error	Mariete Rendon (b) (4)	21 Oct 2020 14:58:34
User coded data point as SOC: Cardiac disorders, HLT: Cardiac arrhythmias, HLT: Supraventricular arrhythmias, PT: Atrial fibrillation, LLT: Atrial fibrillation aggravated - 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)	20 Oct 2020 13:31:42
Data point term sent to Coder	(b) (4)	
User entered 'atrial fibrillation exacerbation'	Coder Import (b) (4)	20 Oct 2020 13:31:42
	(b) (4)	
	System	20 Oct 2020 13:06:33
	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:07
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:12
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:15
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:21
User entered '7 Sep 2020'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:22
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	20 Oct 2020 13:06:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:24
User entered 'No (N)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:27:20
User closed query 'Should this be 15Sep2020' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:27:19
Query 'Should this be 15Sep2020' answered with 'Source verified. Date was corrected.' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 15:57:11
User entered '15 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 15:56:58
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User opened query 'Should this be 15Sep2020' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:07:48
User entered '16 Sep 2020'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Generated On: 09 Jun 2021 15:31:03

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:50
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Form: Adverse Events (3)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	20 Oct 2020 13:06:10

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:51:35
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Grade 3/Severe (Grade 3/Severe)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:54
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:55
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:57
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:07:59
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).		20 Oct 2020 13:20:17
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 by data change (Site from System).		20 Oct 2020 13:20:17
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	20 Oct 2020 13:06:10
User entered 'I'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:08:00
User entered '7 Sep 2020'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	16 Nov 2020 02:27:26
User closed query 'Should this be 15Sep2020?' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:27:24
Query 'Should this be 15Sep2020?' answered with 'Source verified. Date was corrected.' (Site from CRA).	Jessie Downs (b) (4)	13 Nov 2020 15:57:05
	(b) (4)	
User entered '15 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 15:56:58
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User opened query 'Should this be 15Sep2020?' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:08:52
User entered '16 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:07:30
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:13:55
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:20:17
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:13:57
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:13:59
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:01
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:04
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:51:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:51:42
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:08
User entered 'None (NONE)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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None

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:10
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:11
User entered 'I'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:14
User entered '0'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:17
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:14:19
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 13:14:23
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	20 Oct 2020 13:14:23
User entered 'Subject with history of atrial fibrillation since 2017 after mitral valve replacement due to mitral valve replacement history with recent restenosis.' reason for change: Data Entry Error	Mariete Rendon (b) (4)	20 Oct 2020 13:14:23
	(b) (4)	
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	20 Oct 2020 13:06:10
User entered empty.	Mariete Rendon (b) (4)	20 Oct 2020 13:06:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'I'	System	20 Oct 2020 13:06:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'I'	System	20 Oct 2020 13:06:10

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 15:31:03

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	System	20 Oct 2020 13:20:17

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as SOC: Investigations, HLGT: Haematology investigations (incl blood groups), HLT: Coagulation and bleeding analyses, PT: International normalised ratio increased, LLT: International normalized ratio increased - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:01:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	13 Nov 2020 00:01:42
DataPoint Un-verified.	(b) (4), (b) (6)	12 Nov 2020 20:17:48
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:17:42
Data point term sent to Coder	System	12 Nov 2020 20:16:08
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
Data point term sent to Coder	System	12 Nov 2020 20:15:04
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
Data point term sent to Coder	System	04 Nov 2020 20:14:48
User closed query 'DM-Coding: Please edit the term to include a qualifier, for example, increased, decreased, abnormal, normal etc.' (Site from System).	System	04 Nov 2020 20:14:17
Query 'DM-Coding: Please edit the term to include a qualifier, for example, increased, decreased, abnormal, normal etc.' answered with 'Increased' (Site from System).	Mariete Rendon (b) (4) (b) (4)	04 Nov 2020 20:14:17
User entered 'SUPRATHERAPEUTIC INTERNATIONAL NORMALIZED RATIO (Increased)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	04 Nov 2020 20:13:52

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: Please edit the term to include a qualifier, for example, increased, decreased, abnormal, normal etc.' (Site from System). Data point term sent to Coder	Coder Import (b) (4)	22 Oct 2020 09:29:24
User entered 'supratherapeutic international normalized ratio'	System	21 Oct 2020 15:03:03
	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '7 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '11 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	System	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:52:31
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

US3172185

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Number of Days in ICU

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:52:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	08 Jan 2021 15:52:43
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Not Related (NOT RELATED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'None (NONE)'	Mariete Rendon (b) (4)	21 Oct 2020 15:02:15
	(b) (4)	

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'I'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:15:27
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '0'	System	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 15:31:03

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33
User entered '1'	System	21 Oct 2020 15:02:15

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Folder: Adverse Events

Form: Adverse Events (5)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:34:59
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:58
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:56
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:51
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	12 Nov 2020 20:15:38
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	12 Nov 2020 20:14:33

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:31:03

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 20:17:57
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:04

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:30:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:30:06
	(b) (4)	
Data point term sent to Coder	System	18 Aug 2020 20:10:04
User entered 'LISINOPRIL'	Mariete Rendon (b) (4)	18 Aug 2020 20:09:39
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'HYPERTENSION'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '20'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 20:09:39
User entered 'UN UNK 2017'	Mariete Rendon (b) (4)	18 Aug 2020 20:09:39
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Mariete Rendon (b) (4) (b) (4)	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Aug 2020 20:09:39

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
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.	Coder Import (b) (4)	18 Aug 2020 23:30:06
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 23:30:06
	(b) (4)	
Data point term sent to Coder	System	18 Aug 2020 20:10:11
User entered 'METFORMIN'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'DIABETES TYPE 2'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '1000'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'mg (mg)'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'twice daily (BID)'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Oral (ORAL)'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:23:44
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	18 Aug 2020 20:10:06
User entered 'UN UNK 2017'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:25:59
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:25:59
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Yes (Y)'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:25:59
	(b) (4)	
User entered '21 Oct 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:25:59
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Mariete Rendon (b) (4)	18 Aug 2020 20:10:06
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User entered '2'	System	18 Aug 2020 20:10:06

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User entered '1'	System	18 Aug 2020 20:10:06

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:10
User entered '804 (804)'	System	18 Aug 2020 20:10:06

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:49:38
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:49:38
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:30:14
User entered 'furosemide'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:30:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 19:30:08
User entered 'Congestive heart failure' reason for change: Data Entry Error	Jessie Downs (b) (4)	21 Oct 2020 19:30:08
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:29:37
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Per source, 40 mg BID' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:25:41
Query 'Per source, 40 mg BID' answered with 'Source verified. Dose was updated.' (Site from CRA).	Jessie Downs (b) (4)	13 Nov 2020 15:59:36
User entered '40' reason for change: Data Entry Error	(b) (4)	
	Jessie Downs (b) (4)	13 Nov 2020 15:59:17
	(b) (4)	
User opened query 'Per source, 40 mg BID' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:24:42
User entered '80'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Per source, subject was on furosemide from before.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:25:50
Query 'Per source, subject was on furosemide from before.' answered with 'Data was updated in Concomitant medication log.' (Site from CRA).	Jessie Downs (b) (4)	13 Nov 2020 17:41:57
	(b) (4)	
User opened query 'Per source, subject was on furosemide from before.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:24:28
User entered '07 Sep 2020'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:30:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 19:30:13
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	21 Oct 2020 19:30:13
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 19:29:37
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '11 Sep 2020'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 19:29:37
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User entered '2'	System	21 Oct 2020 19:29:37

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User entered '1'	System	21 Oct 2020 19:29:37

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:47:30
User entered '804 (804)'	System	21 Oct 2020 19:29:37

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:19:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 05:19:32
Data point term sent to Coder	System	21 Oct 2020 19:34:23
User entered 'metoprolol'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Congestive heart failure / Atrial fibrillation'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '25'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'three times daily (TID)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:10
User entered '23 Dec 2017' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per source, subject was on this medication since before.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:26:09
Query 'Per source, subject was on this medication since before.' answered with 'Data was added to the concomitant medication log.' (Site from CRA).	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:43:50
User opened query 'Per source, subject was on this medication since before.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:25:29
User entered '07 Sep 2020'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:10
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:10
User entered 'un Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User entered '3'	System	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User entered '1'	System	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:11
User entered '804 (804)'	System	21 Oct 2020 19:33:27

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN SODIUM, PRODUCTSYNONYM: COUMADIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:37:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 19:37:35
Data point term sent to Coder	System	21 Oct 2020 19:36:26
User entered 'Coumadin'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Atrial fibrillation'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '1.75'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:36
User entered '11 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '07 Sep 2020'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:36
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
Signature has been broken.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:36
User entered 'un Jan 2021' reason for change: Data Entry Error	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:27:36
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User entered '1'	System	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User entered '1'	System	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 08:34:16
User entered '804 (804)'	System	21 Oct 2020 19:35:31

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
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.	Coder Import (b) (4)	21 Oct 2020 19:38:39
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 19:38:39
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 19:37:29
User entered 'Amiodarone'	Jessie Downs (b) (4)	21 Oct 2020 19:36:52
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Atrial fibrillation'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '200'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of ATRIAL FIBRILLATION (UN DEC 2017). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:56:16
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of ATRIAL FIBRILLATION (UN DEC 2017). Please review and reconcile Con Med and MH start dates as appropriate. ' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	16 Dec 2020 18:14:20
	(b) (4)	
User entered '13 Jul 2018' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Dec 2020 18:13:58
	(b) (4)	
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition of ATRIAL FIBRILLATION (UN DEC 2017). Please review and reconcile Con Med and MH start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:06:32
User closed query 'Per source, subject was on this medication since before.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:26:27
Query 'Per source, subject was on this medication since before.' answered with 'Data was updated to the concomitant medication log.' (Site from CRA).	Jessie Downs (b) (4)	13 Nov 2020 17:45:33
	(b) (4)	
User entered '13 Jul 2013' reason for change: Data Entry Error	Jessie Downs (b) (4)	13 Nov 2020 17:45:19
	(b) (4)	
User opened query 'Per source, subject was on this medication since before.' (Site from CRA).	(b) (4), (b) (6)	12 Nov 2020 20:26:48
User entered '07 Sep 2020'	Jessie Downs (b) (4)	21 Oct 2020 19:36:52
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 19:36:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 05:07:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 05:07:33
Data point term sent to Coder	System	21 Oct 2020 19:39:36
User entered 'Prednisone'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'RHEUMATOID ARTHRISTIS'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '10'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '07 Sep 2020'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:28:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:28:14
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:28:14
	(b) (4)	
User entered '26 Mar 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:28:14
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 19:39:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User entered '1'	System	21 Oct 2020 19:39:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User entered '1'	System	21 Oct 2020 19:39:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:48
User entered '804 (804)'	System	21 Oct 2020 19:39:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: CANDESARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 20:35:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 20:35:45
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 20:23:18
User entered 'Candesartan'	Jessie Downs (b) (4)	21 Oct 2020 20:22:49
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Congestive Heart Failure - CHF'	Jessie Downs (b) (4)	21 Oct 2020 20:22:49
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '4'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '07 Sep 2020'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:22:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:23:40
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 21:23:40
	(b) (4)	
Data point term sent to Coder	System	21 Oct 2020 20:42:02
User entered 'ENOXAPARIN'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Atrial fibrillation'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '100'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '07 Sep 2020'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:28:57
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:28:57
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	16 Apr 2021 15:29:06
User entered '11 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:29:06
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	16 Apr 2021 15:28:57
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:28:57
	(b) (4)	
User entered '11 Sep 2021' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:28:57
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 20:42:00
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User entered '1'	System	21 Oct 2020 20:42:00

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User entered '1'	System	21 Oct 2020 20:42:00

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:13
User entered '804 (804)'	System	21 Oct 2020 20:42:00

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with Con Med#3-Furosemide (07SEP2020-11SEP2020). Please confirm dates so there is no overlap, or remove duplicates as appropriate.' (Site from DM). Query 'Per DM CLR: Please review the start date of this medication as it overlaps with Con Med#3-Furosemide (07SEP2020-11SEP2020). Please confirm dates so there is no overlap, or remove duplicates as appropriate.' answered with 'Subject has been taking this medication since 23DEC2020. Subject was admitted to the hospital and was administered on 07SEP2020 TO 11SEP2020.' (Site from DM). User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003. User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003. Data point term sent to Coder Coding entries removed.	(b) (4), (b) (6)	21 Dec 2020 03:56:33
	Jessie Downs (b) (4)	16 Dec 2020 18:18:16
	Coder Import (b) (4)	16 Dec 2020 18:17:05
	Coder Import (b) (4)	16 Dec 2020 18:17:05
	System	16 Dec 2020 18:15:44
	Jessie Downs (b) (4)	16 Dec 2020 18:15:36
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with Con Med#3-Furosemide (07SEP2020-11SEP2020). Please confirm dates so there is no overlap, or remove duplicates as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:11:15

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:49:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Oct 2020 21:49:38
Data point term sent to Coder	System	21 Oct 2020 20:44:04
User entered 'furosemide'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:43:09

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Congestive heart failure'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '80'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'twice daily (BID)'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:56:43
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4)	16 Dec 2020 18:19:10
User entered 'Oral (ORAL)' reason for change: Data Entry Error	(b) (4)	16 Dec 2020 18:15:36
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:08:35
User entered 'Subcutaneous (SUBCUTANEOUS)'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '07 Sep 2020'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:29:24
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:29:24
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Yes (Y)'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
Signature has been broken.	Jessie Downs (b) (4)	16 Apr 2021 15:29:24
	(b) (4)	
User entered '11 Sep 2020' reason for change: Data Entry Error	Jessie Downs (b) (4)	16 Apr 2021 15:29:24
	(b) (4)	
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	21 Oct 2020 20:43:09
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User entered '2'	System	21 Oct 2020 20:43:09

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User entered '1'	System	21 Oct 2020 20:43:09

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:46:14
User entered '804 (804)'	System	21 Oct 2020 20:43:09

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 20:45:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Oct 2020 20:45:36
Data point term sent to Coder	System	21 Oct 2020 20:45:08
User entered 'FERROUS SULFATE'	Jessie Downs (b) (4)	21 Oct 2020 20:44:36
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Per DM CLR: Please note that there is no AE 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 AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Dec 2020 03:56:57
Query 'Per DM CLR: Please note that there is no AE 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 AE eCRF if appropriate.' answered with 'Data was updated.' (Site from DM).	Jessie Downs (b) (4) (b) (4)	16 Dec 2020 18:22:57
User opened query 'Per DM CLR: Please note that there is no AE 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 AE eCRF if appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Dec 2020 10:07:44
User entered 'ANEMIA'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '325'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:44:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	21 Oct 2020 20:44:59
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Jessie Downs (b) (4)	21 Oct 2020 20:44:59
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Oct 2020 20:44:36
User entered empty.	Jessie Downs (b) (4)	21 Oct 2020 20:44:36
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Oct 2020 20:44:36

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:17:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 06:17:46
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 17:23:40
User entered 'FUROSEMIDE'	Jessie Downs (b) (4)	13 Nov 2020 17:22:50
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'CHRONIC HEART FAILURE'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '20'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '23 Dec 2017'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 17:22:50

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:25:41
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:25:41
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 17:29:53
User entered 'METOPROLOL'	Jessie Downs (b) (4)	13 Nov 2020 17:29:52
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'CHRONIC HEART FAILURE / Atrial Fibrillation'	Jessie Downs (b) (4)	13 Nov 2020 17:29:52
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '25'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '23 Dec 2017'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '0'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Nov 2020 17:29:52

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: LABETALOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:26:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Nov 2020 05:26:43
	(b) (4)	
Data point term sent to Coder	System	13 Nov 2020 17:32:02
User entered 'LABETALOL'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'ACUTE CHRONIC HEART FAILURE'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '10'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'once (ONCE)'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'Intravenous (INTRAVENOUS)'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '07 Sep 2020'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '07 Sep 2020'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	13 Nov 2020 17:31:56
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User entered empty.	System	13 Nov 2020 17:31:56

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User entered empty.	System	13 Nov 2020 17:31:56

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:15
User entered empty.	System	13 Nov 2020 17:31:56

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
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.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:55:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 15:55:58
Data point term sent to Coder	System	16 Apr 2021 15:55:20
User entered 'metformin'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'diabetes type ii'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '1000'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '11 Sep 2020'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 15:55:12

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 15:59:48
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	16 Apr 2021 15:59:48
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	16 Apr 2021 15:58:33
User entered 'atorvastatin'	Jessie Downs (b) (4)	16 Apr 2021 15:57:32
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'cholesterol'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '40'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '26 Mar 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 15:57:32

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
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), OTHER COMBINATIONS, PRODUCT: SACUBITRIL VALSARTAN SODIUM HYDRATE, PRODUCTSYNONYM: ENTRESTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:18:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Apr 2021 10:18:50
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 15:59:34
User entered 'entrestor'	Jessie Downs (b) (4)	16 Apr 2021 15:58:45
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'hypertension'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '24/26'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'un Jan 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 15:58:45

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: DIAZEPINES, OXAZEPINES, THIAZEPINES AND OXEPINES, PRODUCT: QUETIAPINE FUMARATE, PRODUCTSYNONYM: SEROQUEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:01:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:01:52
Data point term sent to Coder	System	16 Apr 2021 16:00:35
User entered 'seroquel'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'chronic heat failure'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '50'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'un Jan 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 15:59:49

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN CALCIUM, PRODUCTSYNONYM: CRESTOR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:02:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:02:55
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 16:01:36
User entered 'crestor'	Jessie Downs (b) (4)	16 Apr 2021 16:00:47
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'hypcholesterolemia'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '5'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'other (OTHER)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'at bedtime'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'un Jan 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Apr 2021 16:00:47

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:02:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:02:56
Data point term sent to Coder	System	16 Apr 2021 16:01:36
User entered 'Eliquis'	Jessie Downs (b) (4)	16 Apr 2021 16:01:24
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'AFIB'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '5'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'twice daily (BID)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'un Jan 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 16:01:24

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICOID, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:27:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:27:53
Data point term sent to Coder	System	16 Apr 2021 16:03:40
User entered 'prednisone'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'rheumatisms'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '20'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '26 Mar 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 16:02:40

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:04:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:04:06
Data point term sent to Coder	System	16 Apr 2021 16:03:40
User entered 'pantoprazole'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'heartburn'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '40'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '26 Mar 2021'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 16:03:20

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:28:59
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:28:59
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 16:16:01
User entered 'wasfasin'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'afib'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '4'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'un UNK 2019'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '07 Sep 2020'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	16 Apr 2021 16:15:21
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User entered '1'	System	16 Apr 2021 16:15:21

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User entered '1'	System	16 Apr 2021 16:15:21

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:26
User entered '804 (804)'	System	16 Apr 2021 16:15:21

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:27:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:27:53
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 16:18:03
User entered 'prednisone'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'rheumatisms'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '10'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'mg (mg)'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'once daily (QD)'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'Oral (ORAL)'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'un UNK 2017'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '0'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '26 Mar 2021'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	Jessie Downs (b) (4)	16 Apr 2021 16:17:44
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User entered '1'	System	16 Apr 2021 16:17:44

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User entered '1'	System	16 Apr 2021 16:17:44

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:44:28
User entered '804 (804)'	System	16 Apr 2021 16:17:44

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:46:27
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 13:46:27
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 16:21:06
User entered 'ferrous sulfate'	Jessie Downs (b) (4)	16 Apr 2021 16:20:25
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'anemia'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '325'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'un UNK 2017'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 16:20:25

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:24:46
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Apr 2021 16:24:46
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 16:21:06
User entered 'metropolol'	Jessie Downs (b) (4)	16 Apr 2021 16:21:01
	(b) (4)	

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'chf/afib'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '325/50'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'once daily (QD)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'un UNK 2017'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 16:21:01

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
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.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:29:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 16:29:46
Data point term sent to Coder	System	16 Apr 2021 16:29:34
User entered 'Metformin'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'TYPE 2 DIABETES' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 16:29:25
User entered 'Type II Diabetes'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '1000'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'mg (mg)'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'twice daily (BID)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6) (b) (4)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '11 Sep 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	22 Apr 2021 16:23:28
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Apr 2021 16:28:59

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:12:28
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Apr 2021 14:12:28
	(b) (4)	
Data point term sent to Coder	System	16 Apr 2021 16:41:18
User entered 'insulin lispro'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'type 2 diabetes'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'sliding scale'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'Other (OTHER)'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	16 Apr 2021 16:41:16
User entered 'Sliding scale unit' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Apr 2021 16:41:16
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	16 Apr 2021 16:40:54
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '07 Sep 2020'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered '15 Sep 2020'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User signature succeeded.	Mark Kutner (b) (4)	22 Apr 2021 16:23:28
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User entered empty.	System	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User entered empty.	System	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 15:31:03

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:45:24
User entered empty.	System	16 Apr 2021 16:40:54

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:31:03

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:07:06
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:33:07
User entered 'No (N)'	Jessie Downs (b) (4) (b) (4)	01 Sep 2020 19:30:11

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '11 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:33:56

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Transesophageal echocardiogram'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:33:56

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:33:56

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:31:03

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:33:56

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '14 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:34:17

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'cardiac catheterization'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:34:17

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:34:17

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 15:31:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:36:58
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	20 Oct 2020 13:34:17

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 13:45:28
User entered '09 Sep 2020' reason for change: Data Entry Error	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:28
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Oct 2020 13:45:23
User entered '09 Sep 202' (non-conformant).	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:23

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:31:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adult echocardiogram (AE 2D Echo'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:23

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:23

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 15:31:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:02
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:23

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '7 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:57

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:31:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'electrocardiogram'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:57

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:57

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 15:31:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:05
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	21 Oct 2020 13:45:57

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '11 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:20

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:31:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'chest x-ray'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:20

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:20

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 15:31:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:10
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:20

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:31:03

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '7 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:46

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:31:03

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'chest x-ray'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:46

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:31:03

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'Adverse Event (AE)'	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:46

US3172185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 15:31:03

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:37:32
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered empty.	Mariete Rendon (b) (4) (b) (4)	23 Oct 2020 13:13:46

US3172185

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:31:03

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:57:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '14 Sep 2020'	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 15:51:27

US3172185

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:31:03

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:57:39
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'SAE (specify) (SAE)'	Mariete Rendon (b) (4) (b) (4)	28 Sep 2020 15:51:27

US3172185

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:31:03

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 00:57:39
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User closed query 'Per CDM: please record SAE record number instead of details' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 17:08:47
Query 'Per CDM: please record SAE record number instead of details' answered with 'Data updated per query request' (Site from DM).	Mariete Rendon (b) (4)	18 Nov 2020 20:50:10
	(b) (4)	
User entered 'SAE #1' reason for change: Data Entry Error	Mariete Rendon (b) (4)	18 Nov 2020 20:49:59
	(b) (4)	
User opened query 'Per CDM: please record SAE record number instead of details' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 13:23:15
User entered 'due to SAE acute chest pressure'	Mariete Rendon (b) (4)	28 Sep 2020 15:51:27
	(b) (4)	

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '15/Sep/2020 13:33'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'	System	

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '29/Sep/2020 09:17'	System	29 Sep 2020 13:17:54

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	30 Sep 2020 13:53:04
User entered 'I'	(b) (4), (b) (6)	29 Sep 2020 13:17:54

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '30/Sep/2020 13:53'	System	30 Sep 2020 13:53:16

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 15:47:04
User entered 'I'	(b) (4), (b) (6)	30 Sep 2020 13:53:16

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'		

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '19/Oct/2020 15:47'	System	19 Oct 2020 15:47:12

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	19 Oct 2020 15:47:20
User entered 'I'	(b) (4), (b) (6)	19 Oct 2020 15:47:12

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '21/Oct/2020 13:51'	System	21 Oct 2020 13:51:21

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	21 Oct 2020 13:51:27
User entered 'I'	(b) (4), (b) (6)	21 Oct 2020 13:51:21

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '22/Oct/2020 13:25'	System	22 Oct 2020 13:25:17

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	22 Oct 2020 13:25:21
User entered 'I'	(b) (4), (b) (6)	22 Oct 2020 13:25:17

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'		

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '23/Oct/2020 12:55'	System	23 Oct 2020 12:55:50

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	26 Oct 2020 15:14:46
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 12:55:50

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'		

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '26/Oct/2020 11:15'	System	26 Oct 2020 15:15:05

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 15:25:59
User entered 'I'	(b) (4), (b) (6)	26 Oct 2020 15:15:05

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered '05/Nov/2020 10:26'	System	05 Nov 2020 15:26:18

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 16:25:31
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 15:26:18

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'		

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '16/Nov/2020 11:26'	System	16 Nov 2020 16:26:12

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:13:03
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 16:26:12

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'		

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '18/Nov/2020 15:13'	System	18 Nov 2020 15:13:31

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
Un-reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:13:31
User entered '1' reason for change: Obvious Correction	(b) (4), (b) (6)	18 Nov 2020 15:13:31
Reviewed for Safety.	(b) (4), (b) (6)	18 Nov 2020 15:13:03
User entered '0'	(b) (4), (b) (6)	16 Nov 2020 16:26:12

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered		
'USA-US118-2020-MRNA-1273-P301000003'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '25/Nov/2020 18:03'	System	25 Nov 2020 23:03:56

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 23:03:56
User entered '0'	(b) (4), (b) (6)	18 Nov 2020 15:13:31

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered	System	15 Sep 2020 17:32:46
'USA-US118-2020-MRNA-1273-P301000003'		

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Serious

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

Death

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Yes (Y)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'No (N)'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Mark'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'Kutner'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 17:33:12
User entered 'FL'	System	15 Sep 2020 17:32:46

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 19:43:36
Reviewed for Safety.	(b) (4), (b) (6)	29 Sep 2020 13:17:45
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:22:38
User entered 'US' (non-conformant).	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 15:31:03

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '13'	System	25 Nov 2020 23:03:56
User entered '12'	System	25 Nov 2020 23:03:56
User entered '11'	System	18 Nov 2020 15:13:31
User entered '10'	System	16 Nov 2020 16:26:12
User entered '9'	System	05 Nov 2020 15:26:18
User entered '8'	System	26 Oct 2020 15:15:05
User entered '7'	System	23 Oct 2020 12:55:50
User entered '6'	System	22 Oct 2020 13:25:17
User entered '5'	System	21 Oct 2020 13:51:21
User entered '4'	System	19 Oct 2020 15:47:12
User entered '3'	System	30 Sep 2020 13:53:16
User entered '2'	System	29 Sep 2020 13:17:54
User entered '1'	System	15 Sep 2020 17:33:19

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 15:31:03

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Mark Kutner (b) (4)	16 Feb 2021 16:18:40
	(b) (4)	
User entered '25/Nov/2020 18:03'	System	25 Nov 2020 23:03:56

US3172185

Folder: SAE USA-US118-2020-MRNA-1273-P301000003

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 15:31:03

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.	Mark Kutner (b) (4) (b) (4)	16 Feb 2021 16:18:40
User entered 'I'	(b) (4), (b) (6)	25 Nov 2020 23:03:56