

US3142185 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 15:28:11

All time stamps listed in this document are displayed in GMT

US3142185

Form: Participant Creation

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

Participant ID

US3142185

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

US3142185

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Date of Birth (MMM yyyy)	(b) (6)1947
Age	73
Age Units	YEARS
Age (Derived)	73
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 18 Apr 2021 20:39:33

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Date of Informed Consent (<i>dd MMM yyyy</i>)	11 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 18 Apr 2021 20:39:33

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	BILATERAL NEARSIGHTED
Start date (dd MMM yyyy)	UN UNK 1963
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 1963
Start Year (derived)	1963
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	ASTIGMATISM
Start date (dd MMM yyyy)	UN UNK 1963
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 1963
Start Year (derived)	1963
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3142185

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	BILATERAL HEARING LOSS
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 (6)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	VERTIGO
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1951
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 1951
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1951
Start Year (derived)	1951
Stop Month and Year (derived)	JAN 1951
Stop Year (derived)	1951

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	CHRONIC COUGH
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	HERNIAS (LOCATION UNKNOWN)
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 (13)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	HYPERCHOLESTEROLEMIA
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 (14)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 2012
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 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	OA IN KNEES
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	HERNIATED DISK
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	BLOOD CLOTS
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 (20)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 AUG 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:08
Height (xxx.x)	71 in
Weight (xxx.x)	165 lb
BMI (xxx.x)	23.06095 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) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

USES PUBLIC GYM

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 18 Apr 2021 20:39:33

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)	False
Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)	False
Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)	False
Resides in a single family home (i.e., detached housing)	False
Other	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

What was the date of randomization? (dd MMM yyyy) 11 AUG 2020

What was the participant's randomization number? 185556

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

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)	11 AUG 2020
Time of assessment (00:00-23:59)	09:08 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 09:08
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	56 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	150 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

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)	11 AUG 2020
Time of assessment (00:00-23:59)	10:20 (24 HR)
Vital Signs Date and Time (derived)	11 AUG 2020 10:20
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	50 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	152 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:39:54

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Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 11 AUG 2020

What was the treatment time? (00:00-23:59) 09:50 (24 HR)

Treatment Date and Time (derived) 11 AUG 2020 09:50

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:39:54

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Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 AUG 2020
Collection time (00:00-23:59)	09:19 (24 HR)
Collection date and time (derived)	11 AUG 2020 09:19

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)			11 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:19	11 AUG 2020 09:19
Nasopharyngeal Swab 2	Yes	09:19	11 AUG 2020 09:19

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 10:25

PC Open Date & Time

11 AUG 2020 10:10

PC Close Date & Time

11 AUG 2020 12:40

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.4 °F

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

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

PC Time Stamp	11 AUG 2020 20:42
PC Open Date & Time	11 AUG 2020 13:35
PC Close Date & Time	12 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

97.8 °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

12 AUG 2020 21:56

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:10

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 21:11

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

97.7 °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

15 AUG 2020 21:15

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 21:37

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 AUG 2020 21:46

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 10:26

PC Open Date & Time

11 AUG 2020 10:10

PC Close Date & Time

11 AUG 2020 12:40

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☒

No ☐

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

1

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

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 20:46

PC Open Date & Time

11 AUG 2020 13:35

PC Close Date & Time

12 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

7

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 21:57

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

6

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 21:12

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

5

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

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 21:12

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

15 AUG 2020 21:16

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

16 AUG 2020 21:37

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

17 AUG 2020 21:46

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 10:27
PC Open Date & Time	11 AUG 2020 10:10
PC Close Date & Time	11 AUG 2020 12:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

No ☒

Yes ☐

PC Time stamp	11 AUG 2020 20:47
PC Open Date & Time	11 AUG 2020 13:35
PC Close Date & Time	12 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 21:58
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

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)

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

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EAB) (1725)

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:13
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 21:17
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 21:38
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

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 ☒

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:47
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3142185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

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)	16 SEP 2020
Time of assessment (00:00-23:59)	07:53 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 07:53
Temperature (xxx.x)	96.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	55 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	143 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 mmHg
Diastolic Blood Pressure units	MMHG

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

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)	16 SEP 2020
Time of assessment (00:00-23:59)	08:56 (24 HR)
Vital Signs Date and Time (derived)	16 SEP 2020 08:56
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	49 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	13 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3142185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 SEP 2020

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

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

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) 16 SEP 2020

What was the treatment time? (00:00-23:59) 08:25 (24 HR)

Treatment Date and Time (derived) 16 SEP 2020 08:25

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

What was the frequency of the study treatment dosing? ONCE

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

US3142185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 SEP 2020

Collection time (00:00-23:59)

08:00 (24 HR)

Collection date and time (derived)

16 SEP 2020 08:00

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)			16 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:04	16 SEP 2020 08:04
Nasopharyngeal Swab 2	Yes	08:04	16 SEP 2020 08:04

US3142185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 SEP 2020 08:58

PC Open Date & Time

16 SEP 2020 08:45

PC Close Date & Time

16 SEP 2020 11:15

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 96.6 °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	16 SEP 2020 21:52
PC Open Date & Time	16 SEP 2020 12:10
PC Close Date & Time	17 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

99.5 °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

17 SEP 2020 21:46

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

99.7 °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

18 SEP 2020 20:26

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

16 SEP 2020 08:58

PC Open Date & Time

16 SEP 2020 08:45

PC Close Date & Time

16 SEP 2020 11:15

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

16 SEP 2020 21:52

PC Open Date & Time

16 SEP 2020 12:10

PC Close Date & Time

17 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

17 SEP 2020 21:49

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 20:27

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 08:59
PC Open Date & Time	16 SEP 2020 08:45
PC Close Date & Time	16 SEP 2020 11:15

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

No ☒

Yes ☐

PC Time stamp	16 SEP 2020 21:53
PC Open Date & Time	16 SEP 2020 12:10
PC Close Date & Time	17 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 21:49
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

111 of 2302

EAB) (1725)

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

		Yes <input type="checkbox"/>
PC Time stamp	18 SEP 2020 20:27	
PC Open Date & Time	18 SEP 2020 12:00	
PC Close Date & Time	19 SEP 2020 11:59	

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

Yes ☐

PC Time stamp

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

EAB) (1725)

115 of 2302

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

Yes ☐

PC Time stamp

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 6

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

Yes ☐

PC Time stamp

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

Yes ☐

PC Time stamp

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3142185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

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

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	12 OCT 2020
Time of assessment (00:00-23:59)	08:05 (24 HR)
Vital Signs Date and Time (derived)	12 OCT 2020 08:05
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3142185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 OCT 2020

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

US3142185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 OCT 2020

Collection time (00:00-23:59)

08:12 (24 HR)

Collection date and time (derived)

12 OCT 2020 08:12

US3142185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

18 OCT 2020 09:52:05

Patient Cloud Open Date & Time

18 OCT 2020 00:01

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 OCT 2020 23:06:05

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 NOV 2020 09:00:04

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 14:25:12

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 22:46:48

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 21:58:51
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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="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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 14:03:19

Patient Cloud Open Date & Time

10 DEC 2020 00:01

Patient Cloud Close Date & Time

14 DEC 2020 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 14:33:21

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 23:10:21

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 JAN 2021 15:12:31
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	11 JAN 2021 23:50:25
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 21:41:29

Patient Cloud Open Date & Time

14 JAN 2021 00:01

Patient Cloud Close Date & Time

18 JAN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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="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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Close Date & Time](#)

25 JAN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 21:25:55

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 FEB 2021 10:24:30

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 FEB 2021 15:27:38
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

28 FEB 2021 17:56:53

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

07 MAR 2021 08:33:28

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

15 MAR 2021 09:56:47

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

18 MAR 2021 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 00:07:10

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 APR 2021 13:56:04
Patient Cloud Open Date & Time	01 APR 2021 00:01
Patient Cloud Close Date & Time	05 APR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

11 APR 2021 09:13:25

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 00:56:00

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

25 APR 2021 08:16:34

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAY 2021 17:57:12

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

27 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

03 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

10 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	23 AUG 2021 23:59
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US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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="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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

04 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
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Patient Cloud Open Date & Time	25 NOV 2021 00:01
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Patient Cloud Close Date & Time	29 NOV 2021 23:59
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US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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="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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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°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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 579

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

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

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

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

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

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

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 663

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

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

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

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

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

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

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

09 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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27 JUN 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 AUG 2022 00:01
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Patient Cloud Close Date & Time	29 AUG 2022 23:59
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US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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="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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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="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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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
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Patient Cloud Close Date & Time	26 SEP 2022 23:59
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US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 ☐

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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 <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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3142185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 15:28:11

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:57:37

US3142185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:32

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:32

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:32

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:32

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3142185

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:33

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3142185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

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.

US3142185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

2 MAR 2021

Collection time (00:00-23:59)

08:20 (24 HR)

Collection date and time (derived)

2 MAR 2021 08:20

US3142185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 18 Apr 2021 20:39:54

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3142185

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3142185

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 15:28:11

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"/>

US3142185

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 15:28:11

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3142185

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

Form: Visit Date

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

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

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

Folder OID	UNBLND_DECIDE
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US3142185

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

Form: Unblinding

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

Date of updated informed consent (*dd MMM yyyy*) 12 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (*dd MMM yyyy*) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3142185

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	13:37 (24 HR)
Collection date and time (derived)	12 JAN 2021 13:37

US3142185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	13:39
Collection Date and Time (derived)	12 JAN 2021 13:39

US3142185

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:42:46

Generated On: 09 Jun 2021 15:28:11

AEID	USA-US064-2020-MRNA-1273-P30 1000001
Adverse event	CLOSED LOOP BOWEL OBSTRUCTION
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)	18 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)	18 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 checked="" type="radio"/> Grade 3/Severe <input 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)	18 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	26 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:42:46

Generated On: 09 Jun 2021 15:28:11

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Apr 2021 02:42:46

Generated On: 09 Jun 2021 15:28:11

PATIENT CONTACTED THE SITE
TO INFORM THEM THAT HE
WAS DIAGNOSED WITH A
CLOSED LOOP BOWEL
OBSTRUCTION AND HAD TO
HAVE SURGERY TO REPAIR.
DIAGNOSIS OF THE
OBSTRUCTION WAS
CONDUCTED ORIGINALLY VIA
CTA OF THE ABDOMEN AND
PELVIS, BUT CONFIRMED BY
LAPAROSCOPIC SURGERY.
DURING SURGERY 85CM OF
ILEUM WAS REMOVED.
PATIENT DID NOT UNDERGO
ANY COMPLICATIONS BUT
REMAINED HOSPITALIZED
UNTIL NORMAL BOWEL
MOVEMENTS AND DIET
RESUMED. PATIENT REPORTED
THAT HE WAS DISCHARGED
FROM THE HOSPITAL ON
26-SEP-2020 WITH NO HOME
DIRECTIVES.

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HERNIATED DISC

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 (1)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2016	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication BENEFIBER

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 2

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

If dose unit is Other, specify TSP

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication POMEGRANATE EXTRACT

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication LYCOPENE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication CORTISONE

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 checked="" type="radio"/>
If route of administration is Other, specify	INTRA-ARTICULAR	
Start date (dd MMM yyyy)	UN DEC 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication LISINOPRIL/HCTZ

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 20/12.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 1990
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) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication HEARTBURN

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2016	
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) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication SIMVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication SYNTHROID

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2012	
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"/>

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication DIPHENHYDRAMINE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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 2006	
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"/>

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication NAPROXEN

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 375

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 (12)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

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

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication SODIUM CHLORIDE 0.9%

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

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

CONTINUOUS

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)	18 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)		18 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"/>

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication MORPHINE

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)	18 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)	18 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 (15)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication GENERAL ANESTHESIA
UNKNOWN

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)	18 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)		18 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 (16)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)		18 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)		18 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"/>

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication OMNIPAUE

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

Dose per administration 350

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)	18 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)		18 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"/>

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication DILAUDID

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)	18 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)		18 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 (19)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

Name of Medication ROCEPHIN

Prophylaxis Yes ☐
No ☒

Indication CLOSED LOOP BOWEL
OBSTRUCTION

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 02:42:47

Generated On: 09 Jun 2021 15:28:11

	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)	18 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)		18 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 Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

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) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 SEP 2020	LAPAROSCOPIC OPEN, SMALL BOWEL RESECTION	Adverse Event	

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 15:28:11

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 15:28:11

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 ☐

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Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

SAEID	USA-US064-2020-MRNA-1273-P301000001
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

SAEID	USA-US064-2020-MRNA-1273-P301000001
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/SEP/2020 10:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

SAEID	USA-US064-2020-MRNA-1273-P301000001
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	23/OCT/2020 20:28
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

SAEID	USA-US064-2020-MRNA-1273-P301000001
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	21/DEC/2020 16:14
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

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 18 Apr 2021 20:39:31

Generated On: 09 Jun 2021 15:28:11

SAEID	USA-US064-2020-MRNA-1273-P301000001
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	RIPLEY
Investigator's Last Name	HOLLISTER
Site Address: Street	4190 EAST WOODMEN ROAD SUITE 210
Site Address: City	COLORADO SPRINGS
Site Address: State	
Site Address: Postal Code	80920
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	20/JAN/2021 18:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3142185 (Prod: Lynn Institute of The Rockies - ERN-PPDS)

US3142185

Form: Participant Creation

Generated On: 09 Jun 2021 15:28:11

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'US3142185'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:34:25

US3142185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:10:38
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:51:34

US3142185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:10:40
User entered '11 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:34:26

US3142185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:10:42
User entered 'Clinic (Clinic)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:51:34

US3142185

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'SCRN'	System	11 Aug 2020 16:51:34

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:12:25
User entered '(b) (6)1947'	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:34:27

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:12:27
User entered '73'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'YEARS'	System	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '73'	System	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:12:28
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 16:52:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 16:52:13
User entered 'Male (M)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:52:13
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 16:52:05
User entered empty.	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:30
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:37
User entered 'l'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:38
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:40
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:41
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:43
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:44
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:46
User entered empty.	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:12:47
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 15:28:11

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:12:52
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:52:05

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:06
User entered '11 Aug 2020'	Meghan York (b) (4)	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Aug 2020'	System	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2020'	System	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 03:25:39
User closed query 'Please verify protocol version' (Site from CRA).		22 Oct 2020 03:25:37
Query 'Please verify protocol version' answered with 'corrected' (Site from CRA).	Jami Wagner (b) (4)	15 Oct 2020 19:04:14
User entered 'Amendment 2 (2)' reason for change: Data Entry Error	(b) (4)	15 Oct 2020 19:00:59
User opened query 'Please verify protocol version' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 21:04:49
DataPoint Un-verified.		01 Oct 2020 21:04:11
DataPoint Verified.		30 Sep 2020 23:13:07
User entered 'Amendment 1 (1)'	Meghan York (b) (4)	11 Aug 2020 15:54:46
	(b) (4)	

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:08
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:10
User entered empty.	Meghan York (b) (4)	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:11
User entered empty.	Meghan York (b) (4)	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:12
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 15:54:46

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4)	30 Sep 2020 23:13:14
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 14:34:26

US3142185

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 15:28:11

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'I'	System	11 Aug 2020 15:54:52

US3142185

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:13:25
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 15:54:52

US3142185

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 15:28:11

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:32
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 16:52:22

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 20:03:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 20:03:38
Data point term sent to Coder	System	14 Oct 2020 20:02:16
DataPoint Un-verified.	Meghan York (b) (4)	14 Oct 2020 20:01:43
Coding entries removed.	Meghan York (b) (4)	14 Oct 2020 20:01:43
User entered 'bilateral NEARSIGHTED' reason for change: Data Entry Error	Meghan York (b) (4)	14 Oct 2020 20:01:43
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:52
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Nearsighted - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:54:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:54:11
Data point term sent to Coder	System	11 Aug 2020 16:53:11
User entered 'nearsighted'	Meghan York (b) (4)	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:52
User entered 'UN UNK 1963'	Meghan York (b) (4)	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:52
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:52
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:13:52
User entered empty.	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:52
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 1963'	System	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '1963'	System	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:52:56

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:52:18
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:50:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:50:39
Data point term sent to Coder	System	14 Oct 2020 18:49:14
Query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 18:48:53
Coding entries removed.	Meghan York (b) (4) (b) (4)	14 Oct 2020 18:48:48
User entered 'Bilateral CATARACTS' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	14 Oct 2020 18:48:48
User opened query 'Per DM CLR: Please specify the location of Cataract (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:41:51
User coded data point as SOC: Eye disorders, HLGT: Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Cataracts - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:55:19
Data point term sent to Coder	System	11 Aug 2020 16:54:12
User entered 'cataracts'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 2018'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4)	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2018'	System	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2018'	System	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:53:19

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:55
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Astigmatism, LLT: Astigmatism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:55:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:55:17
Data point term sent to Coder	System	11 Aug 2020 16:54:18
User entered 'astigmatism'	Meghan York (b) (4)	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:55
User entered 'UN UNK 1963'	Meghan York (b) (4)	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:55
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:55
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:13:55
User entered empty.	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:13:55
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 1963'	System	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '1963'	System	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:53:48

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Per CDM: Please update Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 12:32:41
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Ringing in ears - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 12:20:16
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Oct 2020 12:20:16
Query 'Per CDM: Please update Med History eCRF.' answered with 'DONE' (Site from DM).	Jami Wagner (b) (4)	20 Oct 2020 19:54:28
Data point term sent to Coder	System	20 Oct 2020 19:54:20
Coding entries removed.	Jami Wagner (b) (4)	20 Oct 2020 19:53:43
User entered 'RINGING IN EARS, BILATERAL' reason for change: Data Entry Error	Jami Wagner (b) (4)	20 Oct 2020 19:53:43
User opened query 'Per CDM: Please update Med History eCRF.' (Site from DM).	(b) (4), (b) (6)	20 Oct 2020 18:55:35
User closed query 'Per DM CLR: Please specify the location of Ringing in ears (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).		20 Oct 2020 18:55:35
Query 'Per DM CLR: Please specify the location of Ringing in ears (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'Bilateral' (Site from DM).	Meghan York (b) (4)	14 Oct 2020 18:49:21
User opened query 'Per DM CLR: Please specify the location of Ringing in ears (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:43:23
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Ringing in ears - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 16:55:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	11 Aug 2020 16:55:18
Data point term sent to Coder	System	11 Aug 2020 16:54:20

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
User entered 'ringing in ears'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 2010'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4)	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2010'	System	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2010'	System	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:54:15

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 18:56:14
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:51:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	14 Oct 2020 18:51:41
Data point term sent to Coder	System	14 Oct 2020 18:50:19
Query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	14 Oct 2020 18:49:40
Coding entries removed.	Meghan York (b) (4) (b) (4)	14 Oct 2020 18:49:35
User entered 'bilateral HEARING LOSS' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	14 Oct 2020 18:49:35
User opened query 'Per DM CLR: Please specify the location of Hearing Loss (Right, Left or Bilateral). Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:43:52
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness, LLT: Hearing loss - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:10
Data point term sent to Coder	System	11 Aug 2020 16:55:21
User entered 'hearing loss'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 2017'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2017'	System	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2017'	System	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:54:39

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:00
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:56:09
Data point term sent to Coder	System	11 Aug 2020 16:55:23
User entered 'vertigo'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:00
User entered 'UN UNK 2016'	Meghan York (b) (4)	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:00
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:00
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:00
User entered 'UN UNK 2019'	Meghan York (b) (4)	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:00
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2016'	System	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2016'	System	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2019'	System	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2019'	System	11 Aug 2020 16:55:19

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:04
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:57:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:57:09
Data point term sent to Coder	System	11 Aug 2020 16:56:24
User entered 'tonsillitis'	Meghan York (b) (4)	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:04
User entered 'UN UNK 1951'	Meghan York (b) (4)	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:04
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:04
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:04
User entered 'UN UNK 1951'	Meghan York (b) (4)	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:04
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 1951'	System	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '1951'	System	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 1951'	System	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '1951'	System	11 Aug 2020 16:56:22

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:08
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Dental implantation, LLT: Dental implantation - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:58:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 16:58:12
Data point term sent to Coder	System	11 Aug 2020 16:57:27
User entered 'dental implants'	Meghan York (b) (4)	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:08
User entered 'UN UNK 2010'	Meghan York (b) (4)	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:08
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:08
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:08
User entered empty.	Meghan York (b) (4)	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:08
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2010'	System	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2010'	System	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:56:49

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:11
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:58:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:58:38
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Chronic cough - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:58:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:58:11
Data point term sent to Coder	System	11 Aug 2020 16:57:28
User entered 'chronic cough'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:11
User entered 'UN UNK 2012'	Meghan York (b) (4)	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:11
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:11
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 16:57:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 16:57:29
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:57:29
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 16:57:19
User entered empty.	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:11
User entered empty.	Meghan York (b) (4)	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:11
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2012'	System	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2012'	System	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:57:19

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:17
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:59:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 16:59:23
Data point term sent to Coder	System	11 Aug 2020 16:58:29
User entered 'pneumonia'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:17
User entered 'UN UNK 2015'	Meghan York (b) (4)	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:17
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:17
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:17
User entered empty.	Meghan York (b) (4)	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:17
User entered '0'	Meghan York (b) (4)	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2015'	System	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2015'	System	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 16:57:55

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:25
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Bronchitis, LLT: Bronchitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:08:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:08:16
Data point term sent to Coder	System	11 Aug 2020 17:06:44
User entered 'bronchitis'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:25
User entered 'UN UNK 2015'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:25
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:25
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:25
User entered 'UN UNK 2015'	Meghan York (b) (4)	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:25
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2015'	System	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2015'	System	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2015'	System	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2015'	System	11 Aug 2020 17:06:39

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia NOS - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 12:25:53
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Dec 2020 12:25:53
Data point term sent to Coder	System	01 Dec 2020 20:20:45
User closed query 'CDM-Coding: Please enter the location for HERNIAS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding. ' (Site from System).	System	01 Dec 2020 20:20:30
Query 'CDM-Coding: Please enter the location for HERNIAS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding. ' answered with 'location unknown ' (Site from System).	Meghan York (b) (4)	01 Dec 2020 20:20:30
Coding entries removed.	Meghan York (b) (4)	01 Dec 2020 20:20:20
User entered 'HERNIAS (location unknown)' reason for change: Data Entry Error	Meghan York (b) (4)	01 Dec 2020 20:20:20
User opened query 'CDM-Coding: Please enter the location for HERNIAS in order that the term may be coded accurately and to the appropriate site. Please make your changes to the reported term accordingly in the diagnosis field to enable coding. ' (Site from System).	Coder Import (b) (4)	23 Nov 2020 13:12:51
Data point term sent to Coder	System	19 Oct 2020 18:13:53
User closed query 'For coding purposes, for term HERNIAS, please specify body location. (e.g. Abdominal hernia, Herniated disc, inguinal hernia,etc)' (Site from System).	System	19 Oct 2020 18:13:18

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Query 'For coding purposes, for term HERNIAS, please specify body location. (e.g. Abdominal hernia, Herniated disc, inguinal hernia,etc)' answered with 'location was not specified ' (Site from System).	Meghan York (b) (4)	19 Oct 2020 18:13:18
User closed query 'Per DM CLR: Please specify the location/ type of Hernia. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 05:00:48
User opened query 'For coding purposes, for term HERNIAS, please specify body location. (e.g. Abdominal hernia, Herniated disc, inguinal hernia,etc)' (Site from System).	Coder Import (b) (4)	18 Oct 2020 23:49:23
Query 'Per DM CLR: Please specify the location/ type of Hernia. Update Med History eCRF as appropriate. ' answered with 'location/ type was not specified ' (Site from DM).	Meghan York (b) (4)	14 Oct 2020 18:50:23
User opened query 'Per DM CLR: Please specify the location/ type of Hernia. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:44:38
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:32:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:32:18
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Hernias NEC, PT: Hernia, LLT: Hernia - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:32:05
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 23:32:05
Data point term sent to Coder	System	18 Aug 2020 20:55:21
Query 'For coding purposes, for term HERNIAS, please specify body location. (e.g. Abdominal hernia, Herniated disc, inguinal hernia,etc)' canceled (Site from System).	Coder Import (b) (4)	18 Aug 2020 20:55:11
User opened query 'For coding purposes, for term HERNIAS, please specify body location. (e.g. Abdominal hernia, Herniated disc, inguinal hernia,etc)' (Site from System).	Coder Import (b) (4)	12 Aug 2020 11:33:22
Data point term sent to Coder	System	11 Aug 2020 17:10:51
User entered 'hernias'	Meghan York (b) (4)	11 Aug 2020 17:10:50

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Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 2000'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2000'	System	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2000'	System	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:10:50

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:13:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:13:12
Data point term sent to Coder	System	11 Aug 2020 17:11:52
User entered 'hypercholesterolemia'	Meghan York (b) (4)	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:28
User entered 'UN UNK 2000'	Meghan York (b) (4)	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:28
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:28
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:11:25

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Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:28
User entered empty.	Meghan York (b) (4)	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:28
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2000'	System	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2000'	System	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:11:25

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 04:37:57
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'con meds entered' (Site from DM).	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:26:28
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:45:11
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:14:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:14:17
Data point term sent to Coder	System	11 Aug 2020 17:12:54
User entered 'hypothyroidism'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 2012'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2012'	System	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2012'	System	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:12:20

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:32
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:04:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	18 Aug 2020 19:04:49
Data point term sent to Coder	System	11 Aug 2020 17:12:54
User entered 'OA in knees'	Meghan York (b) (4)	11 Aug 2020 17:12:44

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Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:32
User entered 'UN UNK 2013'	Meghan York (b) (4)	11 Aug 2020 17:12:44

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Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:32
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:32
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:32
User entered empty.	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:32
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2013'	System	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2013'	System	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:12:44

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:15:19
Data point term sent to Coder	System	11 Aug 2020 17:13:55
User entered 'back pain'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:37
User entered 'UN UNK 2016'	Meghan York (b) (4)	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:37
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:37
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:37
User entered empty.	Meghan York (b) (4)	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:37
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2016'	System	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2016'	System	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:13:09

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Herniated disc - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:36:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Aug 2020 11:36:29
Data point term sent to Coder	System	11 Aug 2020 17:13:55
User entered 'herniated disk'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:39
User entered 'UN UNK 2016'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:39
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:39
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:39
User entered empty.	Meghan York (b) (4)	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:39
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2016'	System	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2016'	System	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:13:46

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 04:38:18
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:28:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:28:43
Data point term sent to Coder	System	15 Oct 2020 19:27:44
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' answered with 'con meds entered' (Site from DM).	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:27:00
Coding entries removed.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:26:56
User entered 'hypertension' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:26:56
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:46:00
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:15:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:15:50
Data point term sent to Coder	System	11 Aug 2020 17:14:57
User entered 'high blood pressure'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 1987'	Meghan York (b) (4)	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 1987'	System	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '1987'	System	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:14:18

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User coded data point as SOC: Vascular disorders, HLT: Embolism and thrombosis, HLT: Non-site specific embolism and thrombosis, PT: Thrombosis, LLT: Clot blood - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:15:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 17:15:19
Data point term sent to Coder	System	11 Aug 2020 17:14:56
User entered 'blood clots'	Meghan York (b) (4)	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'UN UNK 2016'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:31:08
Query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF.' answered with 'subject reported no procedures or treatment for this condition' (Site from DM).	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:28:19
User opened query 'Per DM CLR: Please note that stop date is unexpected for reported chronic condition, if patient underwent surgery for reported condition, then please add procedure details to MH eCRF.' (Site from DM).	(b) (4), (b) (6)	02 Sep 2020 15:47:04
User entered 'UN UNK 2016'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2016'	System	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2016'	System	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2016'	System	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2016'	System	11 Aug 2020 17:14:55

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Sep 2020 23:14:45
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:17:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 17:17:16
Data point term sent to Coder	System	11 Aug 2020 17:16:02
User entered 'anxiety'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:45
User entered 'UN UNK 1987'	Meghan York (b) (4)	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:45
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:45
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:45
User entered empty.	Meghan York (b) (4)	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 23:14:45
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 1987'	System	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '1987'	System	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	11 Aug 2020 17:15:19

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
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)	10 Nov 2020 23:47:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 23:47:48
Data point term sent to Coder	System	10 Nov 2020 23:46:59
User entered 'HEARTBURN'	Meghan York (b) (4)	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'un UNK 2003'	(b) (4) Meghan York (b) (4)	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4) (b) (4)	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2003'	System	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2003'	System	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	10 Nov 2020 23:46:48

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 23:48:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 23:48:43
Data point term sent to Coder	System	10 Nov 2020 23:48:00
User entered 'SEASONAL ALLERGIES'	Meghan York (b) (4)	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'un UNK 2006'	(b) (4) Meghan York (b) (4)	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Meghan York (b) (4)	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'Jan 2006'	System	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2006'	System	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	10 Nov 2020 23:47:54

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:26:28
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:26:32
User entered '11 Aug 2020'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:26:47
User entered '09:08'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '11 Aug 2020 09:08'	System	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:26:55
User entered '71' in	Meghan York (b) (4)	11 Aug 2020 17:17:03
DataPoint set to visible.	(b) (4) System	11 Aug 2020 15:54:52

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:26:58
User entered '165' lb	Meghan York (b) (4)	11 Aug 2020 17:17:03
DataPoint set to visible.	(b) (4) System	11 Aug 2020 15:54:52

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
Amendment Manager: User entered '23.06095'	System	16 Sep 2020 23:51:23
User entered '23.1'	System	11 Aug 2020 17:17:03
DataPoint set to visible.	System	11 Aug 2020 15:54:52

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'kg/m2'	System	11 Aug 2020 17:17:03
DataPoint set to visible.	System	11 Aug 2020 15:54:52

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:05
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).		30 Sep 2020 17:16:19
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:26:32
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:18:38
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly. NOTE: Route is not required ' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 15:20:47
User entered '98.2' F	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:23
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:18:38
User entered 'Other (Other)'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:25
User entered empty; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:18:38
User entered 'temporal'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:27
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:18:38
User entered '56'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'bpm'	System	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:28
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:18:38
User entered '16'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'breaths/min'	System	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:31
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:18:38
User entered '150'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'mmHg'	System	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:34
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:18:38
User entered '61'	Meghan York (b) (4)	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'mmHg'	System	11 Aug 2020 17:17:03

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08

US3142185

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08

US3142185

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:40
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:17:14

US3142185

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:05:42
User entered '11 Aug 2020'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:14

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[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:16
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:18
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:20
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Form: Risk of Exposure

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:34:36
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:34:38
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:34:40
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

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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)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:09
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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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)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:06
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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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)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:04
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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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)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:28:01
User entered 'No (N)'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:59
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:27:58
User entered 'Yes (Y)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:27:54
User entered 'uses public gym'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'I'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:34:58
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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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)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:35:00
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:35:02
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:35:04
User entered '0'	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:35:06
User entered '0'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:17:59

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 15:28:11

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:35:12
User entered empty.	Meghan York (b) (4)	11 Aug 2020 17:17:59

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:55
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:18:13

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Folder: Visit 1 Day 1

Form: Visit Date

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:05:57
User entered '11 Aug 2020'	Meghan York (b) (4)	11 Aug 2020 17:18:13

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:06:00
User entered 'Clinic (Clinic)'	Meghan York (b) (4)	11 Aug 2020 17:18:13

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'VISIT1'	System	11 Aug 2020 17:18:13

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '11 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 15:49:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:11

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 03:31:52
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:31:52
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	11 Aug 2020 15:49:23
User entered '185556' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 15:49:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:11

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	11 Aug 2020 15:49:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:11

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)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:18:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:11

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)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:18:42

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Folder: Visit 1 Day 1

Form: Randomization

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Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:18:42

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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)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:18:42

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 15:28:11

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:18:42

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Folder: Visit 1 Day 1

Form: Randomization

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Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Nov 2020 03:38:07
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	03 Nov 2020 21:06:30
User entered 'No (N)'	Meghan York (b) (4) (b) (4)	03 Nov 2020 21:06:23
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:07:02
DataPoint set to visible.	System	15 Oct 2020 19:00:59
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 06:28:12

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:06:11
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 17:16:29
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:26:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:19:10
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:47:12
User entered '71' in	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:19:10
User entered '165' lb	Meghan York (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:06:11
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 17:16:29
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:26:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:19:10
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:47:12
User entered '71' in	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:19:10
User entered '165' lb	Meghan York (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User accepted default value 'Pre-Dose (PREDOSE)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '11 Aug 2020'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '09:08'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '11 Aug 2020 09:08'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '98.2' F	Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Other (Other)'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'temporal'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '56'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'bpm'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '16'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'breaths/min'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '150'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '61'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:11

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:06:11
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).		30 Sep 2020 17:16:29
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' answered with 'done' (Site from DM).	Meghan York (b) (4) (b) (4)	25 Sep 2020 19:26:40
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4) (b) (4)	21 Sep 2020 18:19:10
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for HEIGHT and WEIGHT. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 12:47:12
User entered '71' in	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 15:28:11

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:06:15
User entered missing code ND - Not Done; reason for change Data Entry Error	Meghan York (b) (4)	21 Sep 2020 18:19:10
User entered '165' lb	Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User accepted default value 'Post-Dose (POSTDOSE)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '11 Aug 2020'	Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 16:51:03
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).		11 Aug 2020 17:21:43
User entered '10:20'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '11 Aug 2020 10:20'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '98.1' F	Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Other (Other)'	Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'temporal'	(b) (4) Meghan York (b) (4) (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '50'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'bpm'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '16'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'breaths/min'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '152'	Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '75'	(b) (4) Meghan York (b) (4)	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	11 Aug 2020 17:21:43

US3142185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Meghan York (b) (4)	25 Sep 2020 19:26:49
User entered 'Yes (Y)'	(b) (4)	
	Meghan York (b) (4)	11 Aug 2020 17:21:53
	(b) (4)	

US3142185

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty; reason for change Data Entry Error	(b) (4)	
	Meghan York (b) (4)	25 Sep 2020 19:26:49
User entered '11 Aug 2020'	(b) (4)	
	Meghan York (b) (4)	11 Aug 2020 17:21:53
	(b) (4)	

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:36:51
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:36:53
User entered empty.	Meghan York (b) (4)	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

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)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:36:55
User entered empty.	Meghan York (b) (4)	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'MRNA-1273 OR PLACEBO'	System	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:36:58
User entered '11 Aug 2020'	Meghan York (b) (4)	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:37:07
User entered '09:50'	Meghan York (b) (4)	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '11 Aug 2020 09:50'	System	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:37:09
User entered 'Left Arm (LEFT ARM)'	Meghan York (b) (4)	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
DataPoint Verified.		28 Oct 2020 19:37:36
User entered 'ONCE'	System	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'INTRAMUSCULAR'	System	11 Aug 2020 15:55:17

US3142185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:09:20
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:22:09

US3142185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:09:22
User entered '11 Aug 2020'	Meghan York (b) (4)	11 Aug 2020 17:22:09

US3142185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:09:24
User entered '09:19'	Meghan York (b) (4)	11 Aug 2020 17:22:09

US3142185

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '11 Aug 2020 09:19'	System	11 Aug 2020 17:22:09

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:38:21
User entered '11 Aug 2020'	Meghan York (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:38:24
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:38:24
User entered '09:19'	Meghan York (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered '11 Aug 2020 09:19'	System	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Meghan York (b) (4) (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:38:24
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:38:24
User entered '09:19'	Meghan York (b) (4)	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered '11 Aug 2020 09:19'	System	11 Aug 2020 17:22:30

US3142185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:39:05
User entered 'Yes (Y)'	Meghan York (b) (4)	11 Aug 2020 17:22:36

US3142185

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	11 Aug 2020 17:22:36

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:24:51', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '497a63ed-23f7-4fbf-b05e-6061707d192d'	System	11 Aug 2020 16:25:30
User entered 'Yes (Y)'	System	11 Aug 2020 16:25:30

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:25:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '497a63ed-23f7-4fbf-b05e-6061707d192d'	System	11 Aug 2020 16:25:30
User entered '98.1'	System	11 Aug 2020 16:25:30

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:25:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '497a63ed-23f7-4fbf-b05e-6061707d192d'	System	11 Aug 2020 16:25:30
User entered 'No (N)'	System	11 Aug 2020 16:25:30

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:25:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '497a63ed-23f7-4fbf-b05e-6061707d192d'	System	11 Aug 2020 16:25:30
User entered '11 Aug 2020 10:25'	System	11 Aug 2020 16:25:30

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 10:10'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 12:40'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:42:21', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '199f0d91-1320-446d-aa6a-868b741d4f2f'	System	12 Aug 2020 02:42:54
User entered 'Yes (Y)'	System	12 Aug 2020 02:42:54

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:42:29', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '199f0d91-1320-446d-aa6a-868b741d4f2f'	System	12 Aug 2020 02:42:54
User entered '97.4'	System	12 Aug 2020 02:42:54

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:42:36', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '199f0d91-1320-446d-aa6a-868b741d4f2f'	System	12 Aug 2020 02:42:54
User entered 'No (N)'	System	12 Aug 2020 02:42:54

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:42:51', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '199f0d91-1320-446d-aa6a-868b741d4f2f'	System	12 Aug 2020 02:42:54
User entered '11 Aug 2020 20:42'	System	12 Aug 2020 02:42:54

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 2'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:56:20', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '842870af-6f0d-4e24-9d80-70ca7a092d59'	System	13 Aug 2020 03:56:50
User entered 'Yes (Y)'	System	13 Aug 2020 03:56:50

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:56:31', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '842870af-6f0d-4e24-9d80-70ca7a092d59'	System	13 Aug 2020 03:56:50
User entered '97.8'	System	13 Aug 2020 03:56:50

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:56:34', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '842870af-6f0d-4e24-9d80-70ca7a092d59'	System	13 Aug 2020 03:56:50
User entered 'No (N)'	System	13 Aug 2020 03:56:50

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:56:47', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '842870af-6f0d-4e24-9d80-70ca7a092d59'	System	13 Aug 2020 03:56:50
User entered '12 Aug 2020 21:56'	System	13 Aug 2020 03:56:50

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 3'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:08:46', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '636987a8-e126-44a6-836d-2aabf3bc2772'	System	14 Aug 2020 03:10:47
User entered 'Yes (Y)'	System	14 Aug 2020 03:10:47

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:10:18', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '636987a8-e126-44a6-836d-2aabf3bc2772'	System	14 Aug 2020 03:10:47
User entered '97.9'	System	14 Aug 2020 03:10:47

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:10:23', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '636987a8-e126-44a6-836d-2aabf3bc2772'	System	14 Aug 2020 03:10:47
User entered 'No (N)'	System	14 Aug 2020 03:10:47

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:10:44', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '636987a8-e126-44a6-836d-2aabf3bc2772'	System	14 Aug 2020 03:10:47
User entered '13 Aug 2020 21:10'	System	14 Aug 2020 03:10:47

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 4'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'dda25c94-f66d-4101-ab82-219a37d7355e'	System	15 Aug 2020 03:11:44
User entered 'Yes (Y)'	System	15 Aug 2020 03:11:44

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:21', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'dda25c94-f66d-4101-ab82-219a37d7355e'	System	15 Aug 2020 03:11:44
User entered '97.9'	System	15 Aug 2020 03:11:44

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'dda25c94-f66d-4101-ab82-219a37d7355e'	System	15 Aug 2020 03:11:44
User entered 'No (N)'	System	15 Aug 2020 03:11:44

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:40', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'dda25c94-f66d-4101-ab82-219a37d7355e'	System	15 Aug 2020 03:11:44
User entered '14 Aug 2020 21:11'	System	15 Aug 2020 03:11:44

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 5'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:15:36', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd5079d5d-5691-4992-88f6-50dbe7ff9ffb'	System	16 Aug 2020 03:15:58
User entered 'Yes (Y)'	System	16 Aug 2020 03:15:58

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:15:44', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd5079d5d-5691-4992-88f6-50dbe7ff9ffb'	System	16 Aug 2020 03:15:58
User entered '97.7'	System	16 Aug 2020 03:15:58

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:15:47', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd5079d5d-5691-4992-88f6-50dbe7ff9ffb'	System	16 Aug 2020 03:15:58
User entered 'No (N)'	System	16 Aug 2020 03:15:58

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:15:53', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd5079d5d-5691-4992-88f6-50dbe7ff9ffb'	System	16 Aug 2020 03:15:58
User entered '15 Aug 2020 21:15'	System	16 Aug 2020 03:15:58

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 6'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '248e4327-d459-4700-a067-3d88e38d9eb2'	System	17 Aug 2020 03:37:24
User entered 'Yes (Y)'	System	17 Aug 2020 03:37:24

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:09', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '248e4327-d459-4700-a067-3d88e38d9eb2'	System	17 Aug 2020 03:37:24
User entered '97.7'	System	17 Aug 2020 03:37:24

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '248e4327-d459-4700-a067-3d88e38d9eb2'	System	17 Aug 2020 03:37:24
User entered 'No (N)'	System	17 Aug 2020 03:37:24

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:20', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '248e4327-d459-4700-a067-3d88e38d9eb2'	System	17 Aug 2020 03:37:24
User entered '16 Aug 2020 21:37'	System	17 Aug 2020 03:37:24

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 7'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:45:35', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '59ec779a-57e3-4acc-aae0-a2127d3854ac'	System	18 Aug 2020 03:46:08
User entered 'Yes (Y)'	System	18 Aug 2020 03:46:08

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:45:46', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '59ec779a-57e3-4acc-aae0-a2127d3854ac'	System	18 Aug 2020 03:46:08
User entered '98.1'	System	18 Aug 2020 03:46:08

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:45:49', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '59ec779a-57e3-4acc-aae0-a2127d3854ac'	System	18 Aug 2020 03:46:08
User entered 'No (N)'	System	18 Aug 2020 03:46:08

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:06', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '59ec779a-57e3-4acc-aae0-a2127d3854ac'	System	18 Aug 2020 03:46:08
User entered '17 Aug 2020 21:46'	System	18 Aug 2020 03:46:08

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:25:39', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7fec0d-3959-4ea8-abde-f616db1471fe'	System	11 Aug 2020 16:26:33
User entered 'None (1)'	System	11 Aug 2020 16:26:33

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:25:42', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7fec0d-3959-4ea8-abde-f616db1471fe'	System	11 Aug 2020 16:26:33
User entered 'No (N)'	System	11 Aug 2020 16:26:33

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:09', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7fec0d-3959-4ea8-abde-f616db1471fe'	System	11 Aug 2020 16:26:33
User entered 'No (N)'	System	11 Aug 2020 16:26:33

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:16', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7fec0d-3959-4ea8-abde-f616db1471fe'	System	11 Aug 2020 16:26:33
User entered 'None (1)'	System	11 Aug 2020 16:26:33

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:28', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7fec0d-3959-4ea8-abde-f616db1471fe'	System	11 Aug 2020 16:26:33
User entered '11 Aug 2020 10:26'	System	11 Aug 2020 16:26:33

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 10:10'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 12:40'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:43:04', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '184441d7-d5c5-44ae-bd69-d29a3c26656e'	System	12 Aug 2020 02:46:48
User entered 'None (1)'	System	12 Aug 2020 02:46:48

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:45:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '184441d7-d5c5-44ae-bd69-d29a3c26656e'	System	12 Aug 2020 02:46:48
User entered 'Yes (Y)'	System	12 Aug 2020 02:46:48

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:45:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '184441d7-d5c5-44ae-bd69-d29a3c26656e'	System	12 Aug 2020 02:46:48
User entered '1'	System	12 Aug 2020 02:46:48

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:46:07', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '184441d7-d5c5-44ae-bd69-d29a3c26656e'	System	12 Aug 2020 02:46:48
User entered 'No (N)'	System	12 Aug 2020 02:46:48

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:46:20', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '184441d7-d5c5-44ae-bd69-d29a3c26656e'	System	12 Aug 2020 02:46:48
User entered 'None (1)'	System	12 Aug 2020 02:46:48

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:46:44', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '184441d7-d5c5-44ae-bd69-d29a3c26656e'	System	12 Aug 2020 02:46:48
User entered '11 Aug 2020 20:46'	System	12 Aug 2020 02:46:48

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 2'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:56:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ac2c8954-9d2e-49cf-bc69-17740506e873'	System	13 Aug 2020 03:57:43
User entered 'None (1)'	System	13 Aug 2020 03:57:43

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:56:59', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ac2c8954-9d2e-49cf-bc69-17740506e873'	System	13 Aug 2020 03:57:43
User entered 'Yes (Y)'	System	13 Aug 2020 03:57:43

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:09', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ac2c8954-9d2e-49cf-bc69-17740506e873'	System	13 Aug 2020 03:57:43
User entered '7'	System	13 Aug 2020 03:57:43

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ac2c8954-9d2e-49cf-bc69-17740506e873'	System	13 Aug 2020 03:57:43
User entered 'No (N)'	System	13 Aug 2020 03:57:43

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:22', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ac2c8954-9d2e-49cf-bc69-17740506e873'	System	13 Aug 2020 03:57:43
User entered 'None (1)'	System	13 Aug 2020 03:57:43

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:36', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ac2c8954-9d2e-49cf-bc69-17740506e873'	System	13 Aug 2020 03:57:43
User entered '12 Aug 2020 21:57'	System	13 Aug 2020 03:57:43

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 3'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:10:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7c283d-611e-42f4-976f-f1a1b9f6c50f'	System	14 Aug 2020 03:12:07
User entered 'None (1)'	System	14 Aug 2020 03:12:07

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:10:54', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7c283d-611e-42f4-976f-f1a1b9f6c50f'	System	14 Aug 2020 03:12:07
User entered 'Yes (Y)'	System	14 Aug 2020 03:12:07

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:11:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7c283d-611e-42f4-976f-f1a1b9f6c50f'	System	14 Aug 2020 03:12:07
User entered '6'	System	14 Aug 2020 03:12:07

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:11:39', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7c283d-611e-42f4-976f-f1a1b9f6c50f'	System	14 Aug 2020 03:12:07
User entered 'No (N)'	System	14 Aug 2020 03:12:07

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:11:48', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7c283d-611e-42f4-976f-f1a1b9f6c50f'	System	14 Aug 2020 03:12:07
User entered 'None (1)'	System	14 Aug 2020 03:12:07

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:01', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '3f7c283d-611e-42f4-976f-f1a1b9f6c50f'	System	14 Aug 2020 03:12:07
User entered '13 Aug 2020 21:12'	System	14 Aug 2020 03:12:07

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 4'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:48', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0342ee79-49b2-434c-b4e9-a623fe8b170d'	System	15 Aug 2020 03:12:45
User entered 'None (1)'	System	15 Aug 2020 03:12:45

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:51', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0342ee79-49b2-434c-b4e9-a623fe8b170d'	System	15 Aug 2020 03:12:45
User entered 'Yes (Y)'	System	15 Aug 2020 03:12:45

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:11:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0342ee79-49b2-434c-b4e9-a623fe8b170d'	System	15 Aug 2020 03:12:45
User entered '5'	System	15 Aug 2020 03:12:45

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:04', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0342ee79-49b2-434c-b4e9-a623fe8b170d'	System	15 Aug 2020 03:12:45
User entered 'No (N)'	System	15 Aug 2020 03:12:45

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:10', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0342ee79-49b2-434c-b4e9-a623fe8b170d'	System	15 Aug 2020 03:12:45
User entered 'None (1)'	System	15 Aug 2020 03:12:45

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:42', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0342ee79-49b2-434c-b4e9-a623fe8b170d'	System	15 Aug 2020 03:12:45
User entered '14 Aug 2020 21:12'	System	15 Aug 2020 03:12:45

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 5'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:15:58', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f5206a87-d597-4edc-a3de-08a7e2ccbc5f'	System	16 Aug 2020 03:16:29
User entered 'None (1)'	System	16 Aug 2020 03:16:29

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:01', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f5206a87-d597-4edc-a3de-08a7e2ccbc5f'	System	16 Aug 2020 03:16:29
User entered 'No (N)'	System	16 Aug 2020 03:16:29

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:08', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f5206a87-d597-4edc-a3de-08a7e2ccbc5f'	System	16 Aug 2020 03:16:29
User entered 'No (N)'	System	16 Aug 2020 03:16:29

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f5206a87-d597-4edc-a3de-08a7e2ccbc5f'	System	16 Aug 2020 03:16:29
User entered 'None (1)'	System	16 Aug 2020 03:16:29

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f5206a87-d597-4edc-a3de-08a7e2ccbc5f'	System	16 Aug 2020 03:16:29
User entered '15 Aug 2020 21:16'	System	16 Aug 2020 03:16:29

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 6'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '813323b1-dfcd-4637-8a48-dfed0ddcf7c2'	System	17 Aug 2020 03:37:49
User entered 'None (1)'	System	17 Aug 2020 03:37:49

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:28', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '813323b1-dfcd-4637-8a48-dfed0ddcf7c2'	System	17 Aug 2020 03:37:49
User entered 'No (N)'	System	17 Aug 2020 03:37:49

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:30', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '813323b1-dfcd-4637-8a48-dfed0ddcf7c2'	System	17 Aug 2020 03:37:49
User entered 'No (N)'	System	17 Aug 2020 03:37:49

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:39', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '813323b1-dfcd-4637-8a48-dfed0ddcf7c2'	System	17 Aug 2020 03:37:49
User entered 'None (1)'	System	17 Aug 2020 03:37:49

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:46', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '813323b1-dfcd-4637-8a48-dfed0ddcf7c2'	System	17 Aug 2020 03:37:49
User entered '16 Aug 2020 21:37'	System	17 Aug 2020 03:37:49

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 7'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1deaff13-6fcf-4797-a711-ab279d49c1d0'	System	18 Aug 2020 03:46:41
User entered 'None (1)'	System	18 Aug 2020 03:46:41

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:17', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1deaaff13-6fcf-4797-a711-ab279d49c1d0'	System	18 Aug 2020 03:46:41
User entered 'No (N)'	System	18 Aug 2020 03:46:41

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1deaaff13-6fcf-4797-a711-ab279d49c1d0'	System	18 Aug 2020 03:46:41
User entered 'No (N)'	System	18 Aug 2020 03:46:41

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:33', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1deaaff13-6fcf-4797-a711-ab279d49c1d0'	System	18 Aug 2020 03:46:41
User entered 'None (1)'	System	18 Aug 2020 03:46:41

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:38', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1deaaff13-6fcf-4797-a711-ab279d49c1d0'	System	18 Aug 2020 03:46:41
User entered '17 Aug 2020 21:46'	System	18 Aug 2020 03:46:41

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:33', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'None (0)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:37', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'None (0)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:40', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'None (0)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:44', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'None (0)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:27:11', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'None (0)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:26:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'None (0)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:27:04', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered 'No (N)'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T10:27:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '591d259b-9131-4b12-a24a-5c847ba0bf07'	System	11 Aug 2020 16:27:24
User entered '11 Aug 2020 10:27'	System	11 Aug 2020 16:27:24

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 10:10'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 12:40'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 1, after vaccination (at home)'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:46:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'None (0)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:07', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'None (0)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:10', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'None (0)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'None (0)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'None (0)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:22', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'None (0)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:26', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered 'No (N)'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-11T20:47:36', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '77a5d777-192f-4e2c-a337-aa82ba0dd323'	System	12 Aug 2020 02:47:40
User entered '11 Aug 2020 20:47'	System	12 Aug 2020 02:47:40

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '11 Aug 2020 13:35'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '12 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 2'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:42', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'None (0)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:53', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'None (0)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:57:58', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'None (0)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:58:01', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'None (0)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:58:08', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'None (0)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:58:11', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'None (0)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:58:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered 'No (N)'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-12T21:58:27', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f8ccdab6-8c69-4d4a-8cdc-1190fb4cb20a'	System	13 Aug 2020 03:58:33
User entered '12 Aug 2020 21:58'	System	13 Aug 2020 03:58:33

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '12 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '13 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 3'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:08', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered 'None (0)'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered 'None (0)'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:17', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered 'None (0)'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:23', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74' User entered 'None (0)'	System	14 Aug 2020 03:13:26
	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:33', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered 'None (0)'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:41', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered 'None (0)'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:12:57', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered 'No (N)'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-13T21:13:11', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2aa641ea-6bd2-46c6-99e7-206182f88b74'	System	14 Aug 2020 03:13:26
User entered '13 Aug 2020 21:13'	System	14 Aug 2020 03:13:26

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '13 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '14 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 4'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:47', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'None (0)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:51', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'None (0)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:54', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'None (0)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:12:57', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'None (0)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:13:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'None (0)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:13:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'None (0)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:13:09', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered 'No (N)'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-14T21:13:16', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a23275ed-a4e5-480e-9615-e92429c7112f'	System	15 Aug 2020 03:13:19
User entered '14 Aug 2020 21:13'	System	15 Aug 2020 03:13:19

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '14 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '15 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 5'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:31', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'None (0)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:36', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'None (0)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:39', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'None (0)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:41', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'None (0)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:16:52', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'None (0)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:17:07', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'None (0)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:17:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered 'No (N)'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-15T21:17:21', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '08e960a1-1847-420a-9d52-9ab55e2d6f4d'	System	16 Aug 2020 03:17:28
User entered '15 Aug 2020 21:17'	System	16 Aug 2020 03:17:28

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '15 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 6'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'None (0)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:52', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'None (0)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'None (0)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:57', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'None (0)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:37:59', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'None (0)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:38:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'None (0)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:38:08', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered 'No (N)'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-16T21:38:17', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '17e7f97c-7ee3-4665-a8a0-7dc8f0b740c4'	System	17 Aug 2020 03:38:20
User entered '16 Aug 2020 21:38'	System	17 Aug 2020 03:38:20

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 7'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:43', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'None (0)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'None (0)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:54', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'None (0)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:46:57', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'None (0)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:47:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'None (0)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:47:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'None (0)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:47:11', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered 'No (N)'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-08-17T21:47:18', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a36a778-4722-47fb-88cc-1863e4dc6bdc'	System	18 Aug 2020 03:47:21
User entered '17 Aug 2020 21:47'	System	18 Aug 2020 03:47:21

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Aug 2020 12:00'	System	11 Aug 2020 15:55:17

US3142185

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Aug 2020 11:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	31 Aug 2020 01:32:54

US3142185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Jami Wagner (b) (4)	31 Aug 2020 02:11:27
User entered '20 Aug 2020'	(b) (4)	
	Jami Wagner (b) (4)	31 Aug 2020 01:32:54
	(b) (4)	

US3142185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	31 Aug 2020 02:11:27
reason for change: Data Entry Error	(b) (4)	
User entered 'Contact Not Made (CONTACT NOT MADE)'	Jami Wagner (b) (4)	31 Aug 2020 01:32:54
	(b) (4)	

US3142185

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty; reason for change Data Entry Error	Jami Wagner (b) (4)	31 Aug 2020 02:11:27
User entered 'LM'	Jami Wagner (b) (4)	31 Aug 2020 01:32:54

US3142185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	31 Aug 2020 02:11:36

US3142185

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	31 Aug 2020 02:11:36

US3142185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	31 Aug 2020 03:01:20

US3142185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '27 Aug 2020'	Jami Wagner (b) (4)	31 Aug 2020 03:01:20

US3142185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	31 Aug 2020 03:01:20

US3142185

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	Jami Wagner (b) (4)	31 Aug 2020 03:01:20

US3142185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	31 Aug 2020 03:01:24

US3142185

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	31 Aug 2020 03:01:24

US3142185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:40:43
User entered 'Yes (Y)'	Jami Wagner (b) (4)	10 Sep 2020 21:40:50

US3142185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:40:43
User entered '02 Sep 2020'	Jami Wagner (b) (4)	10 Sep 2020 21:40:50

US3142185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:40:43
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	10 Sep 2020 21:40:50

US3142185

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:40:43
User entered empty.	Jami Wagner (b) (4)	10 Sep 2020 21:40:50

US3142185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:40:54
User entered 'Yes (Y)'	Jami Wagner (b) (4)	10 Sep 2020 21:40:57

US3142185

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	10 Sep 2020 21:40:57

US3142185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:10:02
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 23:44:06

US3142185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:03
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).		22 Sep 2020 17:08:16
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Information provided is correct.' (Site from System).	Shelby Pickle (b) (4)	16 Sep 2020 23:44:16
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	16 Sep 2020 23:44:06
User entered '16 Sep 2020'	Shelby Pickle (b) (4)	16 Sep 2020 23:44:06

US3142185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:06
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	16 Sep 2020 23:44:06

US3142185

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'VISIT2'	System	16 Sep 2020 23:44:06

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User accepted default value 'Pre-Dose (PREDOSE)'	Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '07:53'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '16 Sep 2020 07:53'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '96.9' F	Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '55'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'bpm'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '12'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'breaths/min'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '143'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '66'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User accepted default value 'Post-Dose (POSTDOSE)'	Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '16 Sep 2020'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '08:56'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '16 Sep 2020 08:56'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '97.4' F	Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Other (Other)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Temporal'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '49'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'bpm'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '13'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'breaths/min'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '142'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '78'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	16 Sep 2020 23:45:26

US3142185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:45:35

US3142185

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '16 Sep 2020'	Shelby Pickle (b) (4)	16 Sep 2020 23:45:35

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:17
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:19
User entered empty.	Shelby Pickle (b) (4)	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

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)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:20
User entered empty.	Shelby Pickle (b) (4)	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'MRNA-1273 OR PLACEBO'	System	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:22
User entered '16 Sep 2020'	Shelby Pickle (b) (4)	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:24
User entered '08:25'	Shelby Pickle (b) (4)	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '16 Sep 2020 08:25'	System	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:30
User entered 'Left Arm (LEFT ARM)'	Shelby Pickle (b) (4)	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
DataPoint Verified.		01 Oct 2020 21:10:33
User entered 'ONCE'	System	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 15:28:11

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'INTRAMUSCULAR'	System	16 Sep 2020 14:34:09

US3142185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:53
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	16 Sep 2020 23:45:49

US3142185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:10:55
User entered '16 Sep 2020'	Shelby Pickle (b) (4)	16 Sep 2020 23:45:49

US3142185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 21:10:57
User entered '08:00'	Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 23:45:49

US3142185

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '16 Sep 2020 08:00'	System	16 Sep 2020 23:45:49

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 21:11:03
User entered '16 Sep 2020'	Shelby Pickle (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '08:04'	Shelby Pickle (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '16 Sep 2020 08:04'	System	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shelby Pickle (b) (4) (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '08:04'	Shelby Pickle (b) (4)	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '16 Sep 2020 08:04'	System	16 Sep 2020 23:46:07

US3142185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	16 Sep 2020 23:46:12

US3142185

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'I'	System	16 Sep 2020 23:46:12

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:57:47', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b38a5f82-1db4-4afc-8334-f58b3400fbde'	System	16 Sep 2020 14:58:41
User entered 'Yes (Y)'	System	16 Sep 2020 14:58:41

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:57:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b38a5f82-1db4-4afc-8334-f58b3400fbde' User entered '97.4'	System	16 Sep 2020 14:58:41
	System	16 Sep 2020 14:58:41

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b38a5f82-1db4-4afc-8334-f58b3400fbde'	System	16 Sep 2020 14:58:41
User entered 'No (N)'	System	16 Sep 2020 14:58:41

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:12', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b38a5f82-1db4-4afc-8334-f58b3400fbde'	System	16 Sep 2020 14:58:41
User entered '16 Sep 2020 08:58'	System	16 Sep 2020 14:58:41

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 08:45'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 11:15'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:51:24', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2ebd1a05-c7ff-4e12-b364-0fa32f18989a'	System	17 Sep 2020 03:52:26
User entered 'Yes (Y)'	System	17 Sep 2020 03:52:26

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2ebd1a05-c7ff-4e12-b364-0fa32f18989a'	System	17 Sep 2020 03:52:26
User entered '96.6'	System	17 Sep 2020 03:52:26

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:18', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2ebd1a05-c7ff-4e12-b364-0fa32f18989a'	System	17 Sep 2020 03:52:26
User entered 'No (N)'	System	17 Sep 2020 03:52:26

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:24', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '2ebd1a05-c7ff-4e12-b364-0fa32f18989a'	System	17 Sep 2020 03:52:26
User entered '16 Sep 2020 21:52'	System	17 Sep 2020 03:52:26

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 12:10'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 2'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:45:59', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1c07aba6-e8ed-4157-a23c-e2b111323815'	System	18 Sep 2020 03:46:25
User entered 'Yes (Y)'	System	18 Sep 2020 03:46:25

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:46:09', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1c07aba6-e8ed-4157-a23c-e2b111323815'	System	18 Sep 2020 03:46:25
User entered '99.5'	System	18 Sep 2020 03:46:25

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:46:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1c07aba6-e8ed-4157-a23c-e2b111323815'	System	18 Sep 2020 03:46:25
User entered 'No (N)'	System	18 Sep 2020 03:46:25

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:46:21', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1c07aba6-e8ed-4157-a23c-e2b111323815'	System	18 Sep 2020 03:46:25
User entered '17 Sep 2020 21:46'	System	18 Sep 2020 03:46:25

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 3'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:18', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5a285892-5905-417e-aaef-1201e4c40ecc'	System	19 Sep 2020 02:29:58
User entered 'Yes (Y)'	System	19 Sep 2020 02:29:58

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:26', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5a285892-5905-417e-aaef-1201e4c40ecc' User entered '99.7'	System	19 Sep 2020 02:29:58
	System	19 Sep 2020 02:29:58

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:36', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5a285892-5905-417e-aaef-1201e4c40ecc'	System	19 Sep 2020 02:29:58
User entered 'No (N)'	System	19 Sep 2020 02:29:58

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:40', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5a285892-5905-417e-aaef-1201e4c40ecc'	System	19 Sep 2020 02:29:58
User entered '18 Sep 2020 20:26'	System	19 Sep 2020 02:29:58

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 4'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 5'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 6'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 7'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:17', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '239053f0-460a-41cc-82be-41183bfaa87f'	System	16 Sep 2020 14:58:47
User entered 'None (1)'	System	16 Sep 2020 14:58:47

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:22', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '239053f0-460a-41cc-82be-41183bfaa87f'	System	16 Sep 2020 14:58:47
User entered 'No (N)'	System	16 Sep 2020 14:58:47

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:26', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '239053f0-460a-41cc-82be-41183bfaa87f'	System	16 Sep 2020 14:58:47
User entered 'No (N)'	System	16 Sep 2020 14:58:47

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:35', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '239053f0-460a-41cc-82be-41183bfaa87f'	System	16 Sep 2020 14:58:47
User entered 'None (1)'	System	16 Sep 2020 14:58:47

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:41', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '239053f0-460a-41cc-82be-41183bfaa87f'	System	16 Sep 2020 14:58:47
User entered '16 Sep 2020 08:58'	System	16 Sep 2020 14:58:47

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 08:45'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 11:15'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:30', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e4b43329-d24e-4f30-b341-c7976353a672'	System	17 Sep 2020 03:52:52
User entered 'None (1)'	System	17 Sep 2020 03:52:52

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:33', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e4b43329-d24e-4f30-b341-c7976353a672'	System	17 Sep 2020 03:52:52
User entered 'No (N)'	System	17 Sep 2020 03:52:52

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:37', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e4b43329-d24e-4f30-b341-c7976353a672'	System	17 Sep 2020 03:52:52
User entered 'No (N)'	System	17 Sep 2020 03:52:52

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:43', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e4b43329-d24e-4f30-b341-c7976353a672'	System	17 Sep 2020 03:52:52
User entered 'None (1)'	System	17 Sep 2020 03:52:52

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:48', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e4b43329-d24e-4f30-b341-c7976353a672'	System	17 Sep 2020 03:52:52
User entered '16 Sep 2020 21:52'	System	17 Sep 2020 03:52:52

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 12:10'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 2'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:46:30', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0e163628-d13b-4adc-9bfb-c9744cabdbb2'	System	18 Sep 2020 03:49:06
User entered 'Does not interfere with activity (2)'	System	18 Sep 2020 03:49:06

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:48:39', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0e163628-d13b-4adc-9bfb-c9744cabdbb2'	System	18 Sep 2020 03:49:06
User entered 'No (N)'	System	18 Sep 2020 03:49:06

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:48:38', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0e163628-d13b-4adc-9bfb-c9744cabdbb2'	System	18 Sep 2020 03:49:06
User entered 'No (N)'	System	18 Sep 2020 03:49:06

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:48:37', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0e163628-d13b-4adc-9bfb-c9744cabdbb2'	System	18 Sep 2020 03:49:06
User entered 'None (1)'	System	18 Sep 2020 03:49:06

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:03', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '0e163628-d13b-4adc-9bfb-c9744cabdbb2'	System	18 Sep 2020 03:49:06
User entered '17 Sep 2020 21:49'	System	18 Sep 2020 03:49:06

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 3'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:46', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ecc3776b-8b28-4c12-8431-4854eeea49e9'	System	19 Sep 2020 02:30:22
User entered 'None (1)'	System	19 Sep 2020 02:30:22

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ecc3776b-8b28-4c12-8431-4854eeea49e9'	System	19 Sep 2020 02:30:22
User entered 'No (N)'	System	19 Sep 2020 02:30:22

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:26:53', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ecc3776b-8b28-4c12-8431-4854eeea49e9'	System	19 Sep 2020 02:30:22
User entered 'No (N)'	System	19 Sep 2020 02:30:22

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ecc3776b-8b28-4c12-8431-4854eeea49e9'	System	19 Sep 2020 02:30:22
User entered 'None (1)'	System	19 Sep 2020 02:30:22

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:06', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ecc3776b-8b28-4c12-8431-4854eeea49e9'	System	19 Sep 2020 02:30:22
User entered '18 Sep 2020 20:27'	System	19 Sep 2020 02:30:22

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 4'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 5'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 6'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 7'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:50', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'None (0)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:56', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'None (0)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:58:59', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'None (0)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:59:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'None (0)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:59:05', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'None (0)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:59:07', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'None (0)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:59:23', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered 'No (N)'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T08:59:37', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '52d1fcf5-615b-485b-a102-b562da908969'	System	16 Sep 2020 14:59:37
User entered '16 Sep 2020 08:59'	System	16 Sep 2020 14:59:37

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 08:45'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 11:15'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 1, after vaccination (at home)'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:52:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19'	System	17 Sep 2020 03:53:34
User entered 'None (0)'	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:04', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19'	System	17 Sep 2020 03:53:34
User entered 'None (0)'	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:08', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19' User entered 'None (0)'	System	17 Sep 2020 03:53:34
	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:10', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19' User entered 'None (0)'	System	17 Sep 2020 03:53:34
	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19' User entered 'None (0)'	System	17 Sep 2020 03:53:34
	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:16', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19'	System	17 Sep 2020 03:53:34
User entered 'None (0)'	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:23', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19'	System	17 Sep 2020 03:53:34
User entered 'No (N)'	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-16T21:53:31', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '34282be2-d055-44c7-8ba0-4576ba42ac19'	System	17 Sep 2020 03:53:34
User entered '16 Sep 2020 21:53'	System	17 Sep 2020 03:53:34

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '16 Sep 2020 12:10'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 2'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:11', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'None (0)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:15', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'None (0)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:20', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'None (0)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:23', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'None (0)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:26', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'None (0)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:28', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'None (0)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:35', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered 'No (N)'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-17T21:49:45', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'ef701455-7d9a-44a7-877f-19cb54ec6c02'	System	18 Sep 2020 03:49:47
User entered '17 Sep 2020 21:49'	System	18 Sep 2020 03:49:47

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '17 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 3'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:13', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'None (0)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:16', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'None (0)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'None (0)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:22', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'None (0)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:27', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'None (0)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:30', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'None (0)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:38', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered 'Yes (Y)'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-09-18T20:27:49', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '202ffe29-41f2-4394-a381-820d502ce295'	System	19 Sep 2020 02:30:38
User entered '18 Sep 2020 20:27'	System	19 Sep 2020 02:30:38

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '18 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '19 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 4'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '19 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '20 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 5'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '20 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '21 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 6'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '21 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '22 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	16 Sep 2020 14:34:09
User entered 'Day 7'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

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)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '22 Sep 2020 12:00'	System	16 Sep 2020 14:34:09

US3142185

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 15:28:11

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
User entered '23 Sep 2020 11:59'	System	16 Sep 2020 14:34:09

US3142185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 22:45:58
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	28 Sep 2020 19:29:33

US3142185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 22:46:00
User entered '24 Sep 2020'	Dalia Jeronimo (b) (4)	28 Sep 2020 19:29:33

US3142185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 22:46:02
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	28 Sep 2020 19:29:33

US3142185

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	30 Sep 2020 22:46:04
User entered empty.	Dalia Jeronimo (b) (4)	28 Sep 2020 19:29:33

US3142185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	28 Sep 2020 19:29:37

US3142185

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	28 Sep 2020 19:29:37

US3142185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:43:07
User entered 'Yes (Y)'	Jami Wagner (b) (4)	06 Oct 2020 17:02:39

US3142185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:43:09
User entered '30 Sep 2020'	Jami Wagner (b) (4)	06 Oct 2020 17:02:39

US3142185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:43:11
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	06 Oct 2020 17:02:39

US3142185

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:43:16
User entered empty.	Jami Wagner (b) (4)	06 Oct 2020 17:02:39

US3142185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	06 Oct 2020 17:02:48

US3142185

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	06 Oct 2020 17:02:48

US3142185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:33:44

US3142185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '7 Oct 2020'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:33:44

US3142185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:33:44

US3142185

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	Dalia Jeronimo (b) (4)	08 Oct 2020 15:33:44

US3142185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:42:36
User entered 'Yes (Y)'	Dalia Jeronimo (b) (4)	08 Oct 2020 15:33:29

US3142185

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	08 Oct 2020 15:33:29

US3142185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:44:24
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	14 Oct 2020 20:55:33

US3142185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:44:24
User entered '12 Oct 2020'	Shelby Pickle (b) (4)	14 Oct 2020 20:55:33

US3142185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:44:24
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	14 Oct 2020 20:55:33

US3142185

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'VISIT3'	System	14 Oct 2020 20:55:33

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:44:46
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:44:48
User entered '12 Oct 2020'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:44:56
User entered '08:05'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '12 Oct 2020 08:05'	System	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:47
User entered '98.2' F	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:48
User entered 'Other (Other)'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:50
User entered 'Temporal'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:52
User entered '63'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'bpm'	System	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:54
User entered '14'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'breaths/min'	System	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:56
User entered '125'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:47:59
User entered '80'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'mmHg'	System	14 Oct 2020 20:56:01

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55

US3142185

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55

US3142185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:48:11
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:10

US3142185

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:48:13
User entered '12 Oct 2020'	Shelby Pickle (b) (4)	14 Oct 2020 20:56:10

US3142185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:48:24
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	14 Oct 2020 20:57:14

US3142185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Nov 2020 05:48:05
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:48:28
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you ' answered with 'Information is correct. Unscheduled lab kit was used for this visit due to lack of supplies ' (Site from DM).	Meghan York (b) (4) (b) (4)	23 Oct 2020 15:50:37
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 12OCT2020 is recorded under Visit 3 Day 57 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:02:17
User entered '12 Oct 2020'	Shelby Pickle (b) (4) (b) (4)	14 Oct 2020 20:57:14

US3142185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:48:31
User entered '08:12'	Shelby Pickle (b) (4)	14 Oct 2020 20:57:14

US3142185

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered '12 Oct 2020 08:12'	System	14 Oct 2020 20:57:14

US3142185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	14 Oct 2020 20:57:25

US3142185

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:55
User entered 'I'	System	14 Oct 2020 20:57:25

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 64'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Please 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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Please 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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Please 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 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '11 Oct 2020 00:01'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 03:38:44
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '15 Oct 2020 23:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 71'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-10-18T09:51:52', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'edb16cb0-769a-4857-bc18-7bb129e21ee0'	System	18 Oct 2020 15:52:08
User entered 'No (N)'	System	18 Oct 2020 15:52:08

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-10-18T09:51:57', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'edb16cb0-769a-4857-bc18-7bb129e21ee0'	System	18 Oct 2020 15:52:08
User entered 'No (N)'	System	18 Oct 2020 15:52:08

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-10-18T09:52:05', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'edb16cb0-769a-4857-bc18-7bb129e21ee0' User entered '18 Oct 2020 09:52:05'	System	18 Oct 2020 15:52:08
	System	18 Oct 2020 15:52:08

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '18 Oct 2020 00:01'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '22 Oct 2020 23:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 78'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-10-25T23:05:53', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '4d6e2f3a-43e0-4078-9047-870317a7a609'	System	26 Oct 2020 05:06:07
User entered 'No (N)'	System	26 Oct 2020 05:06:07

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-10-25T23:05:57', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '4d6e2f3a-43e0-4078-9047-870317a7a609'	System	26 Oct 2020 05:06:07
User entered 'No (N)'	System	26 Oct 2020 05:06:07

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-10-25T23:06:05', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '4d6e2f3a-43e0-4078-9047-870317a7a609'	System	26 Oct 2020 05:06:07
User entered '25 Oct 2020 23:06:05'	System	26 Oct 2020 05:06:07

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '25 Oct 2020 00:01'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '29 Oct 2020 23:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 92'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-08T08:59:44', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '00d29d39-b8fb-4ae6-b732-4a70a83ee6e1'	System	08 Nov 2020 16:00:07
User entered 'No (N)'	System	08 Nov 2020 16:00:07

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-08T08:59:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '00d29d39-b8fb-4ae6-b732-4a70a83ee6e1'	System	08 Nov 2020 16:00:07
User entered 'No (N)'	System	08 Nov 2020 16:00:07

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-08T09:00:04', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '00d29d39-b8fb-4ae6-b732-4a70a83ee6e1'	System	08 Nov 2020 16:00:07
User entered '08 Nov 2020 09:00:04'	System	08 Nov 2020 16:00:07

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '08 Nov 2020 00:01'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '12 Nov 2020 23:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered 'Day 99'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-18T14:24:53', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '10bb3f57-f0ea-4b0a-97f6-73689697b3d1'	System	18 Nov 2020 21:25:13
User entered 'No (N)'	System	18 Nov 2020 21:25:13

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-18T14:25:01', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '10bb3f57-f0ea-4b0a-97f6-73689697b3d1'	System	18 Nov 2020 21:25:13
User entered 'No (N)'	System	18 Nov 2020 21:25:13

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-18T14:25:12', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '10bb3f57-f0ea-4b0a-97f6-73689697b3d1'	System	18 Nov 2020 21:25:13
User entered '18 Nov 2020 14:25:12'	System	18 Nov 2020 21:25:13

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '15 Nov 2020 00:01'	System	11 Aug 2020 15:55:17

US3142185

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:47:36
Data entry locked.	System	11 Aug 2020 15:55:17
User entered '19 Nov 2020 23:59'	System	11 Aug 2020 15:55:17

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2020-11-23T22:46:26', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '8a848250-7f86-459f-afe7-e70863ef1053'	System	24 Nov 2020 05:46:52
User entered 'No (N)'	System	24 Nov 2020 05:46:52

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2020-11-23T22:46:45', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '8a848250-7f86-459f-afe7-e70863ef1053'	System	24 Nov 2020 05:46:52
User entered 'No (N)'	System	24 Nov 2020 05:46:52

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-23T22:46:48', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '8a848250-7f86-459f-afe7-e70863ef1053'	System	24 Nov 2020 05:46:52
User entered '23 Nov 2020 22:46:48'	System	24 Nov 2020 05:46:52

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2020-11-29T21:58:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a6aae438-ec7d-4a00-afdf-7e00065c89c3'	System	30 Nov 2020 04:58:53
User entered 'No (N)'	System	30 Nov 2020 04:58:53

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2020-11-29T21:58:45', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a6aae438-ec7d-4a00-afdf-7e00065c89c3'	System	30 Nov 2020 04:58:53
User entered 'No (N)'	System	30 Nov 2020 04:58:53

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-11-29T21:58:51', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'a6aae438-ec7d-4a00-afdf-7e00065c89c3'	System	30 Nov 2020 04:58:53
User entered '29 Nov 2020 21:58:51'	System	30 Nov 2020 04:58:53

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2020-12-11T14:03:06', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a66b9ac-4e42-4d2e-a6bd-3690696ec4b8'	System	11 Dec 2020 21:03:24
User entered 'No (N)'	System	11 Dec 2020 21:03:24

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2020-12-11T14:03:14', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a66b9ac-4e42-4d2e-a6bd-3690696ec4b8'	System	11 Dec 2020 21:03:24
User entered 'No (N)'	System	11 Dec 2020 21:03:24

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-12-11T14:03:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7a66b9ac-4e42-4d2e-a6bd-3690696ec4b8'	System	11 Dec 2020 21:03:24
User entered '11 Dec 2020 14:03:19'	System	11 Dec 2020 21:03:24

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2020-12-20T14:33:02', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '09d035f7-f02b-44e2-b7a1-884b3b0e7884'	System	20 Dec 2020 21:33:24
User entered 'No (N)'	System	20 Dec 2020 21:33:24

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2020-12-20T14:33:15', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '09d035f7-f02b-44e2-b7a1-884b3b0e7884'	System	20 Dec 2020 21:33:24
User entered 'No (N)'	System	20 Dec 2020 21:33:24

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-12-20T14:33:21', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '09d035f7-f02b-44e2-b7a1-884b3b0e7884' User entered '20 Dec 2020 14:33:21'	System	20 Dec 2020 21:33:24
	System	20 Dec 2020 21:33:24

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2020-12-26T23:10:04', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd1538efb-9ff1-4a40-be3c-1d4e4a0b2713'	System	27 Dec 2020 06:10:27
User entered 'No (N)'	System	27 Dec 2020 06:10:27

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2020-12-26T23:10:16', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd1538efb-9ff1-4a40-be3c-1d4e4a0b2713'	System	27 Dec 2020 06:10:27
User entered 'No (N)'	System	27 Dec 2020 06:10:27

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2020-12-26T23:10:21', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'd1538efb-9ff1-4a40-be3c-1d4e4a0b2713'	System	27 Dec 2020 06:10:27
User entered '26 Dec 2020 23:10:21'	System	27 Dec 2020 06:10:27

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-01-04T15:12:24', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b643453b-1b57-4a26-bdf9-d79502cb7a14'	System	04 Jan 2021 22:12:33
User entered 'No (N)'	System	04 Jan 2021 22:12:33

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-01-04T15:12:28', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b643453b-1b57-4a26-bdf9-d79502cb7a14'	System	04 Jan 2021 22:12:33
User entered 'No (N)'	System	04 Jan 2021 22:12:33

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-01-04T15:12:31', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b643453b-1b57-4a26-bdf9-d79502cb7a14'	System	04 Jan 2021 22:12:33
User entered '04 Jan 2021 15:12:31'	System	04 Jan 2021 22:12:33

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-01-11T23:49:30', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f856d816-f0a4-4e37-9e81-f6eacf48783a'	System	12 Jan 2021 06:50:28
User entered 'Yes (Y)'	System	12 Jan 2021 06:50:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-01-11T23:49:35', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f856d816-f0a4-4e37-9e81-f6eacf48783a'	System	12 Jan 2021 06:50:28
User entered 'No (N)'	System	12 Jan 2021 06:50:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-01-11T23:49:45', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f856d816-f0a4-4e37-9e81-f6eacf48783a'	System	12 Jan 2021 06:50:28
User entered 'No (N)'	System	12 Jan 2021 06:50:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-01-11T23:50:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f856d816-f0a4-4e37-9e81-f6eacf48783a'	System	12 Jan 2021 06:50:28
User entered 'No (N)'	System	12 Jan 2021 06:50:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-01-11T23:50:25', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'f856d816-f0a4-4e37-9e81-f6eacf48783a'	System	12 Jan 2021 06:50:28
User entered '11 Jan 2021 23:50:25'	System	12 Jan 2021 06:50:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-01-18T21:40:59', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '64f9fae0-8e9a-46b7-afd1-8cbb28ffaa07'	System	19 Jan 2021 04:41:31
User entered 'No (N)'	System	19 Jan 2021 04:41:31

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-01-18T21:41:08', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '64f9fae0-8e9a-46b7-afd1-8cbb28ffaa07'	System	19 Jan 2021 04:41:31
User entered 'No (N)'	System	19 Jan 2021 04:41:31

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-01-18T21:41:29', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '64f9fae0-8e9a-46b7-afd1-8cbb28ffaa07'	System	19 Jan 2021 04:41:31
User entered '18 Jan 2021 21:41:29'	System	19 Jan 2021 04:41:31

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-01-31T21:25:40', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'fb4e0f27-6e5d-4dbf-b99c-49e75727a3b6'	System	01 Feb 2021 04:25:57
User entered 'No (N)'	System	01 Feb 2021 04:25:57

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-01-31T21:25:46', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'fb4e0f27-6e5d-4dbf-b99c-49e75727a3b6'	System	01 Feb 2021 04:25:57
User entered 'No (N)'	System	01 Feb 2021 04:25:57

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-01-31T21:25:55', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'fb4e0f27-6e5d-4dbf-b99c-49e75727a3b6'	System	01 Feb 2021 04:25:57
User entered '31 Jan 2021 21:25:55'	System	01 Feb 2021 04:25:57

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-02-13T10:24:12', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7aee3fea-108f-46cf-b046-cd2b141bacb0'	System	13 Feb 2021 17:24:35
User entered 'No (N)'	System	13 Feb 2021 17:24:35

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-02-13T10:24:19', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7aee3fea-108f-46cf-b046-cd2b141bacb0'	System	13 Feb 2021 17:24:35
User entered 'No (N)'	System	13 Feb 2021 17:24:35

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-02-13T10:24:30', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '7aee3fea-108f-46cf-b046-cd2b141bacb0'	System	13 Feb 2021 17:24:35
User entered '13 Feb 2021 10:24:30'	System	13 Feb 2021 17:24:35

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-02-20T15:27:27', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e772cf1f-20c8-4df4-a9c8-40ee6733c159'	System	20 Feb 2021 22:27:42
User entered 'No (N)'	System	20 Feb 2021 22:27:42

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-02-20T15:27:33', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e772cf1f-20c8-4df4-a9c8-40ee6733c159'	System	20 Feb 2021 22:27:42
User entered 'No (N)'	System	20 Feb 2021 22:27:42

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-02-20T15:27:38', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'e772cf1f-20c8-4df4-a9c8-40ee6733c159'	System	20 Feb 2021 22:27:42
User entered '20 Feb 2021 15:27:38'	System	20 Feb 2021 22:27:42

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-02-28T17:56:45-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '20ccdbeb-66fe-4a4c-8e21-bf2c7bdef2c7'	System	01 Mar 2021 00:56:57
User entered 'No (N)'	System	01 Mar 2021 00:56:57

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-02-28T17:56:49-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '20ccdbeb-66fe-4a4c-8e21-bf2c7bdef2c7'	System	01 Mar 2021 00:56:57
User entered 'No (N)'	System	01 Mar 2021 00:56:57

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-02-28T17:56:53-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '20ccdbeb-66fe-4a4c-8e21-bf2c7bdef2c7'	System	01 Mar 2021 00:56:57
User entered '28 Feb 2021 17:56:53'	System	01 Mar 2021 00:56:57

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-03-07T08:33:19-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5d0b0680-1634-40d1-a976-62e72cbccfb6'	System	07 Mar 2021 15:33:34
User entered 'No (N)'	System	07 Mar 2021 15:33:34

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-03-07T08:33:25-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5d0b0680-1634-40d1-a976-62e72cbccfb6'	System	07 Mar 2021 15:33:34
User entered 'No (N)'	System	07 Mar 2021 15:33:34

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-03-07T08:33:28-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '5d0b0680-1634-40d1-a976-62e72cbccfb6' User entered '07 Mar 2021 08:33:28'	System	07 Mar 2021 15:33:34
	System	07 Mar 2021 15:33:34

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-03-15T09:56:35-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b5624497-ec5a-4773-afc0-fd347045a026'	System	15 Mar 2021 15:56:49
User entered 'No (N)'	System	15 Mar 2021 15:56:49

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-03-15T09:56:41-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b5624497-ec5a-4773-afc0-fd347045a026'	System	15 Mar 2021 15:56:49
User entered 'No (N)'	System	15 Mar 2021 15:56:49

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-03-15T09:56:47-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: 'b5624497-ec5a-4773-afc0-fd347045a026'	System	15 Mar 2021 15:56:49
User entered '15 Mar 2021 09:56:47'	System	15 Mar 2021 15:56:49

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-03-28T00:06:59-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '26398877-a477-4f74-b9c2-a0bd56c28a7a' User entered 'No (N)'	System	28 Mar 2021 06:07:12
	System	28 Mar 2021 06:07:12

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-03-28T00:07:04-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '26398877-a477-4f74-b9c2-a0bd56c28a7a'	System	28 Mar 2021 06:07:12
User entered 'No (N)'	System	28 Mar 2021 06:07:12

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-03-28T00:07:10-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '26398877-a477-4f74-b9c2-a0bd56c28a7a' User entered '28 Mar 2021 00:07:10'	System	28 Mar 2021 06:07:12
	System	28 Mar 2021 06:07:12

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-04-04T13:55:43-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1d9ec499-93d6-4926-a372-827dc6d84754'	System	04 Apr 2021 19:56:09
User entered 'No (N)'	System	04 Apr 2021 19:56:09

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-04-04T13:55:59-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1d9ec499-93d6-4926-a372-827dc6d84754'	System	04 Apr 2021 19:56:09
User entered 'No (N)'	System	04 Apr 2021 19:56:09

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-04-04T13:56:04-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1d9ec499-93d6-4926-a372-827dc6d84754'	System	04 Apr 2021 19:56:09
User entered '04 Apr 2021 13:56:04'	System	04 Apr 2021 19:56:09

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-04-11T09:13:17-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1d96c62e-9fbf-465b-9900-a69beb8aa1bd'	System	11 Apr 2021 15:13:28
User entered 'No (N)'	System	11 Apr 2021 15:13:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-04-11T09:13:22-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1d96c62e-9fbf-465b-9900-a69beb8aa1bd'	System	11 Apr 2021 15:13:28
User entered 'No (N)'	System	11 Apr 2021 15:13:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-04-11T09:13:25-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '1d96c62e-9fbf-465b-9900-a69beb8aa1bd'	System	11 Apr 2021 15:13:28
User entered '11 Apr 2021 09:13:25'	System	11 Apr 2021 15:13:28

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-04-19T00:55:41-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '960da5a0-3411-409d-99a8-f426e12221d0'	System	19 Apr 2021 06:56:04
User entered 'No (N)'	System	19 Apr 2021 06:56:04

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-04-19T00:55:52-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '960da5a0-3411-409d-99a8-f426e12221d0'	System	19 Apr 2021 06:56:04
User entered 'No (N)'	System	19 Apr 2021 06:56:04

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-04-19T00:56:00-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '960da5a0-3411-409d-99a8-f426e12221d0'	System	19 Apr 2021 06:56:04
User entered '19 Apr 2021 00:56:00'	System	19 Apr 2021 06:56:04

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-04-25T08:16:18-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '467749b0-269a-4614-9ad4-031ffab721fa' User entered 'No (N)'	System	25 Apr 2021 14:16:38
	System	25 Apr 2021 14:16:38

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-04-25T08:16:30-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '467749b0-269a-4614-9ad4-031ffab721fa' User entered 'No (N)'	System	25 Apr 2021 14:16:38
	System	25 Apr 2021 14:16:38

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-04-25T08:16:34-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '467749b0-269a-4614-9ad4-031ffab721fa' User entered '25 Apr 2021 08:16:34'	System	25 Apr 2021 14:16:38
	System	25 Apr 2021 14:16:38

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[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 (b9a055898cbe7d8c)', Time: '2021-05-02T17:56:53-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '183f6f3d-71a0-4349-90a1-3ffca608d6e5'	System	02 May 2021 23:57:15
User entered 'No (N)'	System	02 May 2021 23:57:15

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

Have you been exposed to someone with 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 (b9a055898cbe7d8c)', Time: '2021-05-02T17:57:04-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '183f6f3d-71a0-4349-90a1-3ffca608d6e5'	System	02 May 2021 23:57:15
User entered 'No (N)'	System	02 May 2021 23:57:15

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-05-02T17:57:12-06:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '183f6f3d-71a0-4349-90a1-3ffca608d6e5'	System	02 May 2021 23:57:15
User entered '02 May 2021 17:57:12'	System	02 May 2021 23:57:15

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 03:38:44

US3142185

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 15:28:11

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 03:38:44
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 03:38:44

US3142185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:11

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 12:02:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-02-28T17:57:08-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '101c349a-217d-48d9-a31e-6e5b5fadf687'	System	01 Mar 2021 00:57:42
User entered 'No (N)'	System	01 Mar 2021 00:57:42

US3142185

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 15:28:11

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 12:02:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (b9a055898cbe7d8c)', Time: '2021-02-28T17:57:37-07:00', User OID: 'PatientReportedOutcome (US3142185)', ODM File OID: '101c349a-217d-48d9-a31e-6e5b5fadf687' User entered '28 Feb 2021 17:57:37'	System	01 Mar 2021 00:57:42
	System	01 Mar 2021 00:57:42

US3142185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	09 Nov 2020 22:24:49

US3142185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '9 Nov 2020'	Jami Wagner (b) (4)	09 Nov 2020 22:24:49

US3142185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	09 Nov 2020 22:24:49

US3142185

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	(b) (4) Jami Wagner (b) (4)	09 Nov 2020 22:24:49
	(b) (4)	

US3142185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	09 Nov 2020 22:25:26

US3142185

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 06:37:46
User entered 'I'	System	09 Nov 2020 22:25:26

US3142185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Dec 2020 22:56:55

US3142185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '15 Dec 2020'	Jami Wagner (b) (4)	15 Dec 2020 22:56:55

US3142185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	15 Dec 2020 22:56:55

US3142185

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	Jami Wagner (b) (4)	15 Dec 2020 22:56:55

US3142185

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Dec 2020 22:56:44

US3142185

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User entered 'I'	System	15 Dec 2020 22:56:44

US3142185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 18:07:23

US3142185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '11 Jan 2021'	Jami Wagner (b) (4)	12 Jan 2021 18:07:23

US3142185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	12 Jan 2021 18:07:23

US3142185

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	Jami Wagner (b) (4)	12 Jan 2021 18:07:23

US3142185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Jan 2021 18:07:30

US3142185

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User entered 'I'	System	12 Jan 2021 18:07:30

US3142185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Feb 2021 18:35:05

US3142185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '11 Feb 2021'	Jami Wagner (b) (4)	12 Feb 2021 18:35:05

US3142185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Contact Made (CONTACT MADE)'	Jami Wagner (b) (4)	12 Feb 2021 18:35:05

US3142185

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 15:28:11

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered empty.	Jami Wagner (b) (4)	12 Feb 2021 18:35:05

US3142185

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Jami Wagner (b) (4)	12 Feb 2021 18:35:10

US3142185

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:27:39
User entered 'I'	System	12 Feb 2021 18:35:10

US3142185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	Jami Wagner (b) (4)	02 Mar 2021 16:06:29

US3142185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '2 Mar 2021'	Jami Wagner (b) (4)	02 Mar 2021 16:06:29

US3142185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Clinic (Clinic)'	Jami Wagner (b) (4)	02 Mar 2021 16:06:29

US3142185

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'VISIT4'	System	02 Mar 2021 16:06:29

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	(b) (4) Lisa Jackson (b) (4)	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered empty.	System	05 Apr 2021 14:29:48

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08

US3142185

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 15:28:11

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08

US3142185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'No (N)'	(b) (4) Jami Wagner (b) (4) (b) (4)	02 Mar 2021 16:06:34

US3142185

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 15:28:11

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered empty.	Jami Wagner (b) (4)	02 Mar 2021 16:06:34

US3142185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4) (b) (4)	02 Mar 2021 16:06:56

US3142185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '2 Mar 2021'	Jami Wagner (b) (4)	02 Mar 2021 16:06:56

US3142185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered '08:20'	(b) (4) Jami Wagner (b) (4) (b) (4)	02 Mar 2021 16:06:56

US3142185

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered '2 Mar 2021 08:20'	System	02 Mar 2021 16:06:56

US3142185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:55
User entered 'Yes (Y)'	(b) (4) Jami Wagner (b) (4) (b) (4)	02 Mar 2021 16:07:01

US3142185

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 15:28:11

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 17:59:08
User entered 'I'	System	02 Mar 2021 16:07:01

US3142185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:28:23

US3142185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '12 Jan 2021'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:28:23

US3142185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Clinic (Clinic)'	Shelby Pickle (b) (4)	13 Jan 2021 00:28:23

US3142185

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

Form: Visit Date

Generated On: 09 Jun 2021 15:28:11

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 00:28:23

US3142185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '12 Jan 2021'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:28:53

US3142185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '0'	Jami Wagner (b) (4)	09 Apr 2021 17:43:54
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:11:58

US3142185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:28:53

US3142185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
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.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:10
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.' answered with 'Data has been corrected' (Site from DM).	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 17:44:09
User entered 'Amendment 6 or later (Amendment 6 or later)'	Jami Wagner (b) (4) (b) (4)	09 Apr 2021 17:43:54
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.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 17:31:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:11:58

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '12 Jan 2021' reason for change: Data Entry Error	System	13 Jan 2021 00:29:03
User opened query 'Future date has been entered. Please correct.' (Site from System).	Shelby Pickle (b) (4)	13 Jan 2021 00:29:03
User entered '21 Jan 2021'	(b) (4)	
	System	13 Jan 2021 00:28:53
	Shelby Pickle (b) (4)	13 Jan 2021 00:28:53
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:28:53

US3142185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:55:32
User entered 'mRNA-1273 (mRNA-1273)'	System	
	Shelby Pickle (b) (4)	13 Jan 2021 00:28:53
	(b) (4)	

US3142185

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 06:55:32
User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 06:55:32
	Shelby Pickle (b) (4)	13 Jan 2021 00:28:53
	(b) (4)	

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'No (N)'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:28:53

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User entered empty.	System	13 Jan 2021 00:28:53

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

Form: Unblinding

Generated On: 09 Jun 2021 15:28:11

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User entered empty.	System	13 Jan 2021 00:28:53

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:29:19

US3142185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '12 Jan 2021'	Shelby Pickle (b) (4)	13 Jan 2021 00:29:19

US3142185

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '13:37'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:29:19

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 15:28:11

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User entered '12 Jan 2021 13:37'	System	13 Jan 2021 00:29:19

US3142185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:11

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:29:35

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:11

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '12 Jan 2021'	Shelby Pickle (b) (4)	13 Jan 2021 00:29:35

US3142185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:11

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '13:39'	(b) (4) Shelby Pickle (b) (4)	13 Jan 2021 00:29:35

US3142185

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 15:28:11

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:15:28
User entered '12 Jan 2021 13:39'	System	13 Jan 2021 00:29:35

US3142185

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 15:28:11

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:06:57
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	21 Sep 2020 21:46:23

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:42:51
Query 'Please provide hospital records.' canceled (Site from CRA).		19 Nov 2020 19:42:33
User opened query 'Please provide hospital records.' (Site from CRA).		28 Oct 2020 20:03:56
Reviewed for Safety.		22 Sep 2020 14:41:08
User entered	System	22 Sep 2020 14:41:04
'USA-US064-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	22 Sep 2020 14:41:04

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 17:22:08
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Jan 2021 17:22:08
Data point term sent to Coder	System	19 Jan 2021 15:54:52
DataPoint Un-verified.	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
	(b) (4)	
Coding entries removed.	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
	(b) (4)	
User entered 'Closed Loop Bowel Obstruction' reason for change: Data Entry Error	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:42:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Volvulus, LLT: Volvulus - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:36:58
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	28 Sep 2020 21:36:58
	(b) (4)	
Data point term sent to Coder	System	21 Sep 2020 21:51:10
User entered 'Intestinal Torsion'	Shelby Pickle (b) (4)	21 Sep 2020 21:50:50
	(b) (4)	

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '18 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
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	21 Sep 2020 21:59:06
User entered empty; reason for change Data Entry Error	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:59:06
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	21 Sep 2020 21:50:50
User entered '19:30'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:59:06
User entered '18 Sep 2020 19:30'	System	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 21:37:26
User entered 'No (N)' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:37:26
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	22 Oct 2020 21:37:01
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
	(b) (4)	
DataPoint Un-verified.	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
	(b) (4)	
User entered '18 Sep 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:42:51
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).		23 Oct 2020 20:26:55
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	22 Oct 2020 21:39:13
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	22 Oct 2020 21:39:13
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'Provided' (Site from Safety).	Shelby Pickle (b) (4)	22 Oct 2020 21:38:06
	(b) (4)	
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	22 Oct 2020 21:37:01
User entered '26 Sep 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4)	22 Oct 2020 21:37:01
	(b) (4)	
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)	01 Oct 2020 16:31:23
User entered empty.	Shelby Pickle (b) (4)	21 Sep 2020 21:50:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Un-verified.	(b) (4)	
	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
reason for change: Data Entry Error	(b) (4)	
Query 'PV Query: Please confirm the severity, since	(b) (4), (b) (6)	29 Dec 2020 15:25:06
the event lead to hospitalization.' canceled (Site from		
Safety).		
User opened query 'PV Query: Please confirm the		23 Dec 2020 16:10:53
severity, since the event lead to hospitalization.' (Site		
from Safety).		
DataPoint Verified.		19 Nov 2020 19:42:51
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shelby Pickle (b) (4)	21 Sep 2020 21:50:50
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'Yes (Y)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
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).		28 Sep 2020 03:16:08
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 'Patient has not been discharged at this time' (Site from System).	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:51:24
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	21 Sep 2020 21:50:50
User entered 'I'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '18 Sep 2020'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:49:29
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'see narrative for answer - subject remained until normal bowel movements returned' (Site from Safety).	Jill York (b) (4)	29 Apr 2021 23:35:02
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 16:26:25
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		23 Oct 2020 20:27:05
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'Provided' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:38:34
User entered '26 Sep 2020' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:37:26
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:32:02
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'No (N)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered 'Not Related (NOT RELATED)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:11:38
Query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' answered with 'corrected ' (Site from Safety).	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:53:26
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	18 Dec 2020 18:52:56
DataPoint Un-verified.	(b) (4), (b) (6)	19 Nov 2020 19:43:30
DataPoint Verified.		19 Nov 2020 19:42:51
User opened query 'PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to Not Applicable.' (Site from Safety).		28 Oct 2020 15:09:55
User entered 'None (NONE)'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered '0'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on ConMed is available. Update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on ConMed is available. Update eCRF as appropriate.' answered with 'Will add' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:31
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on ConMed is available. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	Shelby Pickle (b) (4) (b) (4)	19 Jan 2021 15:58:37
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 01:38:09
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Awaiting medical records' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:42:51
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 02:41:55
User entered 'I'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:38:50
	(b) (4), (b) (6)	02 Oct 2020 02:25:46
	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on ConProc is available. Update eCRF as appropriate.' (Site from DM). Query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on ConProc is available. Update eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Jan 2021 15:23:00
User opened query 'Per DM CLR - RQ: Site's response noted. However, please keep this query open until information on ConProc is available. Update eCRF as appropriate.' (Site from DM). DataPoint Verified.	Shelby Pickle (b) (4) (b) (4)	19 Jan 2021 15:56:56
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Note, per SAE Narrative, a Surgery was performed. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 01:38:01
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Note, per SAE Narrative, a Surgery was performed. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Awaiting medical records' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:42:51
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy recorded that matches this AE during this timeframe. Note, per SAE Narrative, a Surgery was performed. Please review and add a Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 02:41:57
User entered '1'	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:39:00
	(b) (4), (b) (6)	02 Oct 2020 02:25:40
	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Nov 2020 19:42:51
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).		23 Oct 2020 20:27:19
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'Updated' (Site from Safety).	Shelby Pickle (b) (4)	22 Oct 2020 21:39:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Shelby Pickle (b) (4)	22 Oct 2020 21:39:13
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)	01 Oct 2020 16:32:14
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shelby Pickle (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:42:51
User entered empty.	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:17:03
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).		23 Apr 2021 15:16:34
User closed query 'PV Query: Please provide the surgical report when available, 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).		23 Apr 2021 15:16:29
Query 'PV Query: Please provide the surgical report when available, 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 'faxed to safety 22APR2021 at 17:30 MST' (Site from Safety).	Jill York (b) (4)	22 Apr 2021 23:35:49
Query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' answered with 'too many lab testing and values to include. Site will send records to safety committee' (Site from Safety).	Jill York (b) (4)	22 Apr 2021 21:55:22
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 test done' (Site from Safety).	Jill York (b) (4)	22 Apr 2021 21:54:25
User opened query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).	(b) (4), (b) (6)	28 Jan 2021 17:56:48

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[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)	28 Jan 2021 17:56:38
User closed query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).		20 Jan 2021 18:04:05
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).		20 Jan 2021 18:03:40
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).		20 Jan 2021 18:03:34
Query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' answered with 'Information provided' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	19 Jan 2021 15:56:40
User entered 'PATIENT CONTACTED THE SITE TO INFORM THEM THAT HE WAS DIAGNOSED WITH A CLOSED LOOP BOWEL OBSTRUCTION AND HAD TO HAVE SURGERY TO REPAIR. Diagnosis of the obstruction was conducted originally via CTA of the abdomen and pelvis, but confirmed by laparoscopic surgery. DURING SURGERY 85CM OF ILEUM WAS REMOVED. PATIENT DID NOT UNDERGO ANY COMPLICATIONS BUT REMAINED HOSPITALIZED UNTIL NORMAL BOWEL MOVEMENTS AND DIET RESUMED. PATIENT REPORTED THAT HE WAS DISCHARGED FROM THE HOSPITAL ON 26-SEP-2020 WITH NO HOME DIRECTIVES.' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	19 Jan 2021 15:56:32

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Narrative](#)

Audit	User	Time (GMT)
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 'Surgery on 18Sep2020' (Site from Safety).	Shelby Pickle (b) (4)	19 Jan 2021 15:54:52
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 'Surgical intervention required' (Site from Safety).	Shelby Pickle (b) (4)	19 Jan 2021 15:54:42
DataPoint Un-verified.	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
User entered 'PATIENT CONTACTED THE SITE TO INFORM THEM THAT HE WAS DIAGNOSED WITH a closed loop bowel obstruction AND HAD TO HAVE SURGERY TO REPAIR. During surgery 85cm of ileum was removed. Patient did not undergo any complications but remained hospitalized until normal bowel movements and diet resumed. PATIENT REPORTED THAT HE WAS DISCHARGED FROM THE HOSPITAL ON 26-SEP-2020 with no home directives.' reason for change: Data Entry Error	Shelby Pickle (b) (4)	19 Jan 2021 15:54:23
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:42:51
User opened query 'PV Query: Please provide any diagnostic or laboratory testing performed to diagnose or monitor the event, with dates performed.' (Site from Safety).		30 Oct 2020 20:13:14
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).		28 Oct 2020 15:09:12

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the surgical report when available, 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)	28 Oct 2020 15:08:19
Query 'PV Query: Please provide the surgical report when available.' canceled (Site from Safety).		28 Oct 2020 15:08:06
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		23 Oct 2020 20:27:38
User closed query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		23 Oct 2020 20:27:35
User entered 'PATIENT CONTACTED THE SITE TO INFORM THEM THAT HE WAS DIAGNOSED WITH INTESTINAL TORSION AND HAD TO HAVE SURGERY TO REPAIR. A large portion of the intestine was resected during the hospitalization. Patient reported that he was discharged from the hospital on 26-Sep-2020. Site has requested complete medical records, awaiting receipt for completion of the AE reporting.' reason for change: Data Entry Error	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:41:21
Query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' answered with 'Awaiting medical records.' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:39:57
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'No pre-disposing risk factors to report' (Site from Safety).	Shelby Pickle (b) (4) (b) (4)	22 Oct 2020 21:39:35
User opened query 'PV Query: Please provide the surgical report when available.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 16:32:45

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[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)	01 Oct 2020 16:32:27
User opened query 'PV Query: Please add concomitant medication received within 30 days prior to event (or >30 days if relevant to event) to concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If none, please state so.' (Site from Safety).		01 Oct 2020 16:31:47
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).		01 Oct 2020 16:31:37
User entered 'Patient contacted the site to inform them that he was diagnosed with intestinal torsion and had to have surgery to repair. The patient remains in the hospital at this time. The site will provide additional information once medical records are available.'	Shelby Pickle (b) (4) (b) (4)	21 Sep 2020 21:50:50

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Sep 2020 21:50:50

US3142185

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 15:28:11

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	21 Sep 2020 21:50:50

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 15:28:11

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 20:04:51
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Oct 2020 19:06:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:19:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:10:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:10:35
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 19:10:03
User entered 'ibuprofen'	Jami Wagner (b) (4)	15 Oct 2020 19:09:05
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:16
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:17
User entered 'herniated disc'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:22
User entered '200'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:20
User entered 'mg (mg)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:27
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:29
User entered 'as needed (PRN)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:31
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:33
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:35
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:37
User entered 'un UNK 2016'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:19:41
User entered '0'	Jami Wagner (b) (4)	15 Oct 2020 19:09:05
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:44
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:46
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:19:48
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:09:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:00
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: DEXTRIN, PRODUCTSYNONYM: BENEFIBER [DEXTRIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:52:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Oct 2020 09:52:45
Data point term sent to Coder	System	15 Oct 2020 19:11:09
User entered 'Benefiber'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 16:28:55
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).		16 Nov 2020 15:24:22
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:26
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:18
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:18
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:51:11
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:20:02
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:05
User entered 'general health'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:13
User entered '2'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:20:15
User entered 'Other (OTHER)'	Jami Wagner (b) (4)	15 Oct 2020 19:10:44
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:16
User entered 'tsp'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:22
User entered 'twice daily (BID)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:25
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:30
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:20:33
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:10:44
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:20:43
User entered 'un UNK 2015'	Jami Wagner (b) (4)	15 Oct 2020 19:10:44
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:45
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:48
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:50
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:20:53
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:10:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:01
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PUNICA GRANATUM, PRODUCTSYNONYM: POMEGRANATE [PUNICA GRANATUM] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 05:29:21
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 Oct 2020 05:29:21
Data point term sent to Coder	System	15 Oct 2020 19:13:11
User entered 'pomegranate Extract'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 16:29:06
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).		16 Nov 2020 15:24:34
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:48
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:40
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:40
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:57:02
DataPoint Verified.		28 Oct 2020 19:21:03
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:05
User entered 'general health'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:08
User entered '250'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:21:11
User entered 'mg (mg)'	Jami Wagner (b) (4)	15 Oct 2020 19:12:48
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:13
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:21:19
User entered 'twice daily (BID)'	Jami Wagner (b) (4)	15 Oct 2020 19:12:48
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:21
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:24
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:21:26
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:12:48
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:28
User entered 'un UNK 2018'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:21:31
User entered '0'	Jami Wagner (b) (4)	15 Oct 2020 19:12:48
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:36
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:39
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:21:43
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:12:48

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:01
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, PRODUCT: LYCOPENE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:15:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:15:46
	(b) (4)	
Data point term sent to Coder	System	15 Oct 2020 19:14:14
User entered 'lycopene'	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Jan 2021 16:29:16
User closed query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).		16 Nov 2020 15:24:47
Query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' answered with 'now corrected ' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:46:05
DataPoint Un-verified.	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:45:55
User opened query 'Per DM CLR: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:52:59
DataPoint Verified.		28 Oct 2020 19:22:03
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'general health'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '30'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'twice daily (BID)'	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un UNK 2018'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4)	15 Oct 2020 19:13:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:13:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
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: HYDROCORTISONE, PRODUCTSYNONYM: CORTISONE [HYDROCORTISONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 14:42:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 14:42:41
DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 19:22:19
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: CORTISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:13:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 21:13:37
Data point term sent to Coder User entered 'cortisone'	System Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:22 15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4)	15 Oct 2020 19:17:04
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'osteoarthritis'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'I'	Jami Wagner (b) (4)	15 Oct 2020 19:17:04
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mL (mL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:17:04
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'as needed (PRN)'	Jami Wagner (b) (4)	15 Oct 2020 19:17:04
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Other (OTHER)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'intra-articular'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un Dec 2019'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4)	15 Oct 2020 19:17:04
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:17:04

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, COMBINATIONS, ATC: ACE INHIBITORS AND DIURETICS, PRODUCT: HYDROCHLOROTHIAZIDE; LISINOPRIL, PRODUCTSYNONYM: LISINOPRIL/HCTZ - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Oct 2020 19:19:31
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Oct 2020 19:19:31
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	15 Oct 2020 19:18:24
User entered 'lisinopril/hctz'	Jami Wagner (b) (4)	15 Oct 2020 19:18:09
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4)	15 Oct 2020 19:18:09
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'hypertension'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '20/12.5'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'once daily (QD)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4)	15 Oct 2020 19:18:09
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:18:09
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:18:34
User entered 'un UNK 1990' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:34
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:18:09
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:18:09

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
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: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:21:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:21:42
Data point term sent to Coder	System	15 Oct 2020 19:20:28
User entered 'omeprazole'	Jami Wagner (b) (4)	15 Oct 2020 19:19:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:25:14
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'now added ' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:47:02
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:56:33
DataPoint Verified.		28 Oct 2020 19:22:19
User entered 'heartburn'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '20'	Jami Wagner (b) (4)	15 Oct 2020 19:19:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4)	15 Oct 2020 19:19:45
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'twice daily (BID)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un UNK 2003'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:19:45

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:22:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	15 Oct 2020 19:22:27
Data point term sent to Coder	System	15 Oct 2020 19:21:31
User entered 'aspirin'	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'heart health'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '81'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'once daily (QD)'	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un UNK 2016'	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4)	15 Oct 2020 19:20:49
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:20:49

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: SIMVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:23:33
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	15 Oct 2020 19:23:33
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	15 Oct 2020 19:22:34
User entered 'simvastatin'	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'hypercholesterolemia'	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '20'	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'once daily (QD)'	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un UNK 2000'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4)	15 Oct 2020 19:22:02
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:22:02

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE SODIUM, PRODUCTSYNONYM: SYNTHROID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:25:44
Data point term sent to Coder	System	15 Oct 2020 19:24:38
User entered 'synthroid'	Jami Wagner (b) (4)	15 Oct 2020 19:23:47
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'hypothyroidism'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '25'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'ug (ug)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:23:47
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'once daily (QD)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:23:47
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:23:47
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un UNK 2012'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Oct 2020 19:23:47
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4)	15 Oct 2020 19:23:47
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Oct 2020 19:23:47

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:26:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Oct 2020 19:26:30
Data point term sent to Coder	System	15 Oct 2020 19:25:40
User entered 'diphenhydramine'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 15:25:45
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'added' (Site from DM).	Meghan York (b) (4) (b) (4)	10 Nov 2020 23:48:05
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. '(Site from DM).	(b) (4), (b) (6)	06 Nov 2020 07:52:21
DataPoint Verified.		28 Oct 2020 19:22:19
User entered 'seasonal allergies'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '25'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4)	15 Oct 2020 19:24:41
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:24:41
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'as needed (PRN)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:24:59
User entered 'un UNK 2006' reason for change: Data Entry Error	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:59
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	15 Oct 2020 19:24:41
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4)	15 Oct 2020 19:24:41
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:24:41
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:24:41

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: NAPROXEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:27:36
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Oct 2020 19:27:36
	(b) (4)	
Data point term sent to Coder User entered 'naproxen'	System	15 Oct 2020 19:26:42
	Jami Wagner (b) (4)	15 Oct 2020 19:25:51
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'osteoarthritis'	Jami Wagner (b) (4)	15 Oct 2020 19:25:51
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '375'	Jami Wagner (b) (4)	15 Oct 2020 19:25:51
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'mg (mg)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'as needed (PRN)'	Jami Wagner (b) (4)	15 Oct 2020 19:25:51
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4)	15 Oct 2020 19:25:51
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Oral (ORAL)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'un Jun 2020'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered '0'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'Yes (Y)'	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered empty.	Jami Wagner (b) (4) (b) (4)	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Oct 2020 19:22:19
User entered 'No (N)'	Jami Wagner (b) (4)	15 Oct 2020 19:25:51
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Oct 2020 19:25:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE, PRODUCTSYNONYM: SODIUM CHLORIDE 0.9% - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 13:46:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Apr 2021 13:46:48
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:04:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 14:04:03
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
Data point term sent to Coder	System	19 Jan 2021 16:00:57
User entered 'Sodium Chloride 0.9%'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'No (N)'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'Closed loop bowel obstruction'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '1000'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'mL (mL)'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered empty.	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'other (OTHER)'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'Continuois'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'Intravenous (INTRAVENOUS)'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered empty.	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '18 Sep 2020'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '0'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'No (N)'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '18 Sep 2020'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'No (N)'	Shelby Pickle (b) (4)	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User entered empty.	System	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User entered empty.	System	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:48
User entered empty.	System	19 Jan 2021 16:00:15

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'Please add additional meds listed on con med SD as appropriate.' (Site from CRA).	(b) (4)	01 Mar 2021 22:06:29
Query 'Please add additional meds listed on con med SD as appropriate.' answered with 'done ' (Site from CRA).	Jill York (b) (4)	22 Feb 2021 18:09:06
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 00:28:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Jan 2021 00:28:11
User opened query 'Please add additional meds listed on con med SD as appropriate.' (Site from CRA).	(b) (4), (b) (6)	19 Jan 2021 16:33:45
DataPoint Verified.		19 Jan 2021 16:30:45
Data point term sent to Coder	System	19 Jan 2021 16:01:58
User entered 'Morphine'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21
	(b) (4)	

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'No (N)'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'Closed Loop Bowel Obstruction'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '4'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'mg (mg)'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered empty.	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'once daily (QD)'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered empty.	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'Intravenous (INTRAVENOUS)'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered empty.	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '18 Sep 2020'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '0'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'No (N)'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered '18 Sep 2020'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 16:30:45
User entered 'No (N)'	Shelby Pickle (b) (4)	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User entered '1'	System	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User entered '1'	System	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:52
User entered '804 (804)'	System	19 Jan 2021 16:01:21

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 10:13:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Apr 2021 10:13:53
Data point term sent to Coder	System	23 Apr 2021 15:53:02
User closed query 'CDM Coding : Per query response, please update the term GENERAL ANESTHESIA - unknown in the medication name field. Thank you.' (Site from System).	System	23 Apr 2021 15:52:32
Query 'CDM Coding : Per query response, please update the term GENERAL ANESTHESIA - unknown in the medication name field. Thank you.' answered with 'done' (Site from System).	Jill York (b) (4)	23 Apr 2021 15:52:32
DataPoint Un-verified.	Jill York (b) (4)	23 Apr 2021 15:52:15
User entered 'GENERAL ANESTHESIA unknown' reason for change: Data Entry Error	Jill York (b) (4)	23 Apr 2021 15:52:15
User opened query 'CDM Coding : Per query response, please update the term GENERAL ANESTHESIA - unknown in the medication name field. Thank you.' (Site from System).	Coder Import (b) (4)	22 Apr 2021 08:50:59
Data point term sent to Coder	System	21 Apr 2021 16:31:38
User closed query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	System	21 Apr 2021 16:30:51
Query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' answered with 'specific type of anesthesia is unknown' (Site from System).	Jill York (b) (4)	21 Apr 2021 16:30:51

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	02 Mar 2021 11:19:43
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
Data point term sent to Coder	System	22 Feb 2021 18:03:57
User entered 'general anesthesia'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'closed loop bowel obstruction'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'unknown'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'Other (OTHER)'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'unknown'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'once (ONCE)'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '0'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User entered empty.	System	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User entered empty.	System	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:22
User entered empty.	System	22 Feb 2021 18:03:44

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:31:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Feb 2021 07:31:08
Data point term sent to Coder	System	22 Feb 2021 18:04:58
User entered 'fentanyl'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'closed loop bowel obstruction'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '50'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'ug (ug)' reason for change: Data Entry Error	Jill York (b) (4)	01 Mar 2021 19:08:27
User entered 'Other (OTHER)'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User closed query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' (Site from DM) DataPoint Verified.	(b) (4) (b) (4), (b) (6)	02 Mar 2021 22:59:32
		01 Mar 2021 22:07:19
Query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' answered with 'corrected ' (Site from DM).	Jill York (b) (4)	01 Mar 2021 19:08:37
User entered empty; reason for change Data Entry Error	Jill York (b) (4)	01 Mar 2021 19:08:27
User opened query 'Per CDM: The dose unit other specify is mentioned as "MCG". However, dose unit "ug" is one of the listed choices. Kindly, update dose unit and keep other specify as blank.' (Site from DM).	(b) (4), (b) (6)	25 Feb 2021 06:08:55
User entered 'mcg'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'once (ONCE)'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '0'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User entered empty.	System	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User entered empty.	System	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:04:59
User entered empty.	System	22 Feb 2021 18:04:55

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOHEXOL, PRODUCTSYNONYM: OMNIPAQUE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 11:36:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 11:36:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
Data point term sent to Coder	System	22 Feb 2021 18:07:00
User entered 'omnipaue'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'closed loop bowel obstruction'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '350'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'mg (mg)'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'once (ONCE)'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '0'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User entered empty.	System	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User entered empty.	System	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:04
User entered empty.	System	22 Feb 2021 18:06:05

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 18:09:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 18:09:00
Data point term sent to Coder	System	22 Feb 2021 18:08:00
User entered 'dilaudid'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'closed loop bowel obstruction'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '0.5'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'mg (mg)'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'once (ONCE)'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '0'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User entered empty.	System	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User entered empty.	System	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:08
User entered empty.	System	22 Feb 2021 18:07:32

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:41:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 07:41:40
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
Data point term sent to Coder	System	22 Feb 2021 18:09:02
User entered 'rocephin'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'closed loop bowel obstruction'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '2'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'g (g)'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'once (ONCE)'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'Intravenous (INTRAVENOUS)'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered empty.	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '0'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered '18 Sep 2020'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User signature succeeded.	Ripley Hollister (b) (4)	26 Apr 2021 02:42:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 22:07:19
User entered 'No (N)'	Jill York (b) (4)	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User entered empty.	System	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User entered empty.	System	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 15:28:11

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:05:13
User entered empty.	System	22 Feb 2021 18:08:34

US3142185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 15:28:11

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:51:20
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'Yes (Y)'	Shelby Pickle (b) (4)	19 Jan 2021 15:57:04

US3142185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:11

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
	(b) (4)	
User entered '18 Sep 2020'	Shelby Pickle (b) (4)	19 Jan 2021 15:57:43
	(b) (4)	

US3142185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:11

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
	(b) (4)	
User entered 'Laparoscopic open, small bowel resection'	Shelby Pickle (b) (4)	19 Jan 2021 15:57:43
	(b) (4)	

US3142185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:11

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
	(b) (4)	
User entered 'Adverse Event (AE)'	Shelby Pickle (b) (4)	19 Jan 2021 15:57:43
	(b) (4)	

US3142185

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 15:28:11

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4) (b) (4)	18 Apr 2021 20:39:34
User entered empty.	Shelby Pickle (b) (4) (b) (4)	19 Jan 2021 15:57:43

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:17
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'USA-US064-2020-MRNA-1273-P301000001'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:18
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:20
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:23
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:24
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:26
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:28
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:35
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:38
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Ripley'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:40
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Hollister'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:42
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '4190 East Woodmen Road Suite 210'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:44
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Colorado Springs'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	20 Jan 2021 18:04:49
User entered empty.	System	20 Jan 2021 18:04:49
Reviewed for Safety.	System	20 Jan 2021 18:04:49
	(b) (4), (b) (6)	20 Jan 2021 18:04:22
DataPoint Verified.		19 Jan 2021 16:34:45
User entered '2855 Dublin Blvd'	Shelby Pickle (b) (4)	19 Jan 2021 15:51:37
	(b) (4)	

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:46
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '80920'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:51
Reviewed for Safety.		23 Oct 2020 20:28:28
User entered 'US'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 18:04:49
User entered '3'	System	21 Dec 2020 21:14:21
User entered '2'	System	23 Oct 2020 20:28:40
User entered '1'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:17
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'USA-US064-2020-MRNA-1273-P301000001'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:18
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:20
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:23
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:24
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:26
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:28
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:35
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:38
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Ripley'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:40
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Hollister'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:42
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '4190 East Woodmen Road Suite 210'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:44
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Colorado Springs'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	20 Jan 2021 18:04:49
User entered empty.	System	20 Jan 2021 18:04:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 18:04:22
DataPoint Verified.		19 Jan 2021 16:34:45
User entered '2855 Dublin Blvd'	Shelby Pickle (b) (4)	19 Jan 2021 15:51:37
	(b) (4)	

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:46
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '80920'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:51
Reviewed for Safety.		23 Oct 2020 20:28:28
User entered 'US'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 18:04:49
User entered '3'	System	21 Dec 2020 21:14:21
User entered '2'	System	23 Oct 2020 20:28:40
User entered '1'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '22/Sep/2020 10:41'	(b) (4) System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 15:28:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 20:28:28
User entered '1'		22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:17
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'USA-US064-2020-MRNA-1273-P301000001'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:18
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:20
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:23
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:24
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:26
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:28
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:35
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4)	28 Oct 2020 19:55:38
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 20:29:37
User entered 'Ripley'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:40
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Hollister'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:42
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '4190 East Woodmen Road Suite 210'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:44
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Colorado Springs'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	20 Jan 2021 18:04:49
User entered empty.	System	20 Jan 2021 18:04:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 18:04:22
DataPoint Verified.		19 Jan 2021 16:34:45
User entered '2855 Dublin Blvd'	Shelby Pickle (b) (4)	19 Jan 2021 15:51:37
	(b) (4)	

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:46
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '80920'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:51
Reviewed for Safety.		23 Oct 2020 20:28:28
User entered 'US'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 18:04:49
User entered '3'	System	21 Dec 2020 21:14:21
User entered '2'	System	23 Oct 2020 20:28:40
User entered '1'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:28:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '23/Oct/2020 20:28'	(b) (4) System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 15:28:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 20:29:37
User entered '1'		23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:17
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'USA-US064-2020-MRNA-1273-P301000001'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:18
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:20
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:23
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:24
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:26
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:28
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:35
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:38
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Ripley'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:40
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Hollister'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:42
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '4190 East Woodmen Road Suite 210'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:44
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Colorado Springs'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	20 Jan 2021 18:04:49
User entered empty.	System	20 Jan 2021 18:04:49
Reviewed for Safety.	System	20 Jan 2021 18:04:49
	(b) (4), (b) (6)	20 Jan 2021 18:04:22
DataPoint Verified.		19 Jan 2021 16:34:45
User entered '2855 Dublin Blvd'	Shelby Pickle (b) (4)	19 Jan 2021 15:51:37
	(b) (4)	

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:46
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '80920'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:51
Reviewed for Safety.		23 Oct 2020 20:28:28
User entered 'US'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 18:04:49
User entered '3'	System	21 Dec 2020 21:14:21
User entered '2'	System	23 Oct 2020 20:28:40
User entered '1'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:28:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '21/Dec/2020 16:14'	(b) (4) System	21 Dec 2020 21:14:21

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 15:28:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 18:04:22
User entered 'I'		21 Dec 2020 21:14:21

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:17
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'USA-US064-2020-MRNA-1273-P301000001'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Serious

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:18
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:20
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:23
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:24
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'Yes (Y)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:26
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:28
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:35
Reviewed for Safety.		22 Sep 2020 14:41:38
User entered 'No (N)'	System	22 Sep 2020 14:41:04

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:38
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Ripley'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:40
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Hollister'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:42
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '4190 East Woodmen Road Suite 210'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:44
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered 'Colorado Springs'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	20 Jan 2021 18:04:49
User entered empty.	System	20 Jan 2021 18:04:49
Reviewed for Safety.	(b) (4), (b) (6)	20 Jan 2021 18:04:22
DataPoint Verified.		19 Jan 2021 16:34:45
User entered '2855 Dublin Blvd'	Shelby Pickle (b) (4)	19 Jan 2021 15:51:37
	(b) (4)	

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:46
Reviewed for Safety.		23 Oct 2020 20:29:37
User entered '80920'	System	23 Oct 2020 20:28:40

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Oct 2020 19:55:51
Reviewed for Safety.		23 Oct 2020 20:28:28
User entered 'US'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 15:28:11

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	20 Jan 2021 18:04:49
User entered '3'	System	21 Dec 2020 21:14:21
User entered '2'	System	23 Oct 2020 20:28:40
User entered '1'	System	22 Sep 2020 14:41:44

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:28:11

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered '20/Jan/2021 18:04'	(b) (4) System	20 Jan 2021 18:04:49

US3142185

Folder: SAE USA-US064-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 15:28:11

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Apr 2021 00:05:16
User signature succeeded.	Ripley Hollister (b) (4)	18 Apr 2021 20:39:34
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Jan 2021 18:04:49