

US3022208 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:49:49

All time stamps listed in this document are displayed in GMT

US3022208

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Participant ID

US3022208

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

US3022208

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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

US3022208

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Date of Birth (MMM yyyy)	(b) (6) 1960
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
Black	True
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) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Date of Informed Consent (<i>dd MMM yyyy</i>)	20 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

US3022208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	POST MENOPAUSAL
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)	_____

US3022208

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	HYPERTENSION
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)	_____

US3022208

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	HEPATITIS C
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022208

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	INSOMNIA
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	BIPOLAR DISORDER
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	BREAST CANCER
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	MASECTOMY
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2014
Start Year (derived)	2014
Stop Month and Year (derived)	JAN 2014
Stop Year (derived)	2014

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Start Year (derived)	1975
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	CHRONIC PAIN GENERALIZED
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3022208

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	CHRONIC CONSTIPTION
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	MORPHINE SULFATE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	SMALL BOWEL OBSTRUCTION
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 (13)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	ABDOMINAL SURGERY
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 (14)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1965
Start Year (derived)	1965
Stop Month and Year (derived)	JAN 1965
Stop Year (derived)	1965

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1975
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 1975
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1975
Start Year (derived)	1975
Stop Month and Year (derived)	JAN 1975
Stop Year (derived)	1975

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Condition	CODEINE ALLERGY
Start date (dd MMM yyyy)	UN UNK 1980
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 1980
Start Year (derived)	1980
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3022208

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:15
Height (xxx.x)	174 cm
Weight (xxx.x)	97.0 kg
BMI (xxx.x)	32.03858 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) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 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: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (*dd MMM yyyy*) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2016

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:43

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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)	True
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	True
Specify	LIVES IN A COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 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) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 106521

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) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Height	ND - Not Done
Weight	ND - Not Done

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

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)	20 AUG 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:15
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	15:50 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:50
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	103 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

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) 20 AUG 2020

What was the treatment time? (00:00-23:59) 15:13 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 15:13

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) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	14:37 (24 HR)
Collection date and time (derived)	20 AUG 2020 14:37

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:49	20 AUG 2020 14:49
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

97.9 °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

20 AUG 2020 15:46

PC Open Date & Time

20 AUG 2020 15:33

PC Close Date & Time

20 AUG 2020 18:03

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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 97.3 °F

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

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

PC Time Stamp	20 AUG 2020 20:49
PC Open Date & Time	20 AUG 2020 18:58
PC Close Date & Time	21 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

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 ☒

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 20:18

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☐

No ☐

Please record your **TEMPERATURE** in °F

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 AUG 2020 13:20

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

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 ☒

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 25 AUG 2020 12:01

PC Open Date & Time 25 AUG 2020 12:00

PC Close Date & Time 26 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

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 ☒

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 26 AUG 2020 20:09

PC Open Date & Time 26 AUG 2020 12:00

PC Close Date & Time 27 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

20 AUG 2020 15:47

PC Open Date & Time

20 AUG 2020 15:33

PC Close Date & Time

20 AUG 2020 18:03

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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

20 AUG 2020 20:49

PC Open Date & Time

20 AUG 2020 18:58

PC Close Date & Time

21 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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)**

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

1

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

21 AUG 2020 20:19

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

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)**

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 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 13:21

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

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

25 AUG 2020 12:02

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

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

26 AUG 2020 20:09

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 15:48
PC Open Date & Time	20 AUG 2020 15:33
PC Close Date & Time	20 AUG 2020 18:03

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:49
PC Open Date & Time	20 AUG 2020 18:58
PC Close Date & Time	21 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

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 ☒

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:20
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

Yes ☐

PC Time stamp

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

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 ☒

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 13:21
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

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)

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US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

Yes ☐

PC Time stamp

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

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 ☒

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EAB) (1725)

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 12:03
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

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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US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 20:09
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

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

Folder OID VISIT2

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

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.

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

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 SAE

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Collection date (dd MMM yyyy)

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

US3022208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:43

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 DEC 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

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	03 DEC 2020
Time of assessment (00:00-23:59)	10:17 (24 HR)
Vital Signs Date and Time (derived)	03 DEC 2020 10:17
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	99 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

03 DEC 2020

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

US3022208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 DEC 2020
Collection time (00:00-23:59)	10:32 (24 HR)
Collection date and time (derived)	03 DEC 2020 10:32

US3022208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:44

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 16:08:35

Patient Cloud Open Date & Time

20 OCT 2020 00:01

Patient Cloud Close Date & Time

24 OCT 2020 23:59

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

27 OCT 2020 20:23:38

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

01 DEC 2020 16:09:39

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have 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	05 DEC 2020 13:04:52
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 15:27:15

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

23 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

28 DEC 2020 12:16:28

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

02 JAN 2021 10:08:49

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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	09 JAN 2021 18:06:22
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 19:11:15

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	24 JAN 2021 16:52:31
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 01:14:10

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

09 FEB 2021 10:07:03

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

22 FEB 2021 15:44:57

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 10:36:10

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 MAR 2021 11:57:44

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

13 MAR 2021 04:11:53

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

21 MAR 2021 13:04:10

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 19:42:45

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

03 APR 2021 15:55:15

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 14:25:58

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

19 APR 2021 06:15:33

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

24 APR 2021 00:02:03

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

01 MAY 2021 16:24:38

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 264

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 MAY 2021 00:01
Patient Cloud Close Date & Time	19 MAY 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 299

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 327

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

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

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

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

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

Fever (Temperature \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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 JUL 2021 00:01
Patient Cloud Close Date & Time	28 JUL 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 355

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2021 00:01
Patient Cloud Close Date & Time	18 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 418

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
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Patient Cloud Close Date & Time	27 OCT 2021 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 NOV 2021 00:01
Patient Cloud Close Date & Time	17 NOV 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 NOV 2021 00:01
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Patient Cloud Close Date & Time	24 NOV 2021 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	15 DEC 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 495

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

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

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

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

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

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

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 502

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2022 00:01
Patient Cloud Close Date & Time	05 JAN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2022 00:01
Patient Cloud Close Date & Time	12 JAN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 FEB 2022 00:01
Patient Cloud Close Date & Time	09 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 635

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 656

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 670

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUN 2022 00:01
Patient Cloud Close Date & Time	29 JUN 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 705

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 726

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	20 AUG 2022 00:01
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Patient Cloud Close Date & Time	24 AUG 2022 23:59
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US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 775

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3022208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:49:49

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		02 MAR 2021 09:54:58

US3022208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 29 Apr 2021 19:02:10

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 JAN 2021

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

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:19:41

Generated On: 09 Jun 2021 14:49:49

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) _____

US3022208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 MAR 2021

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

US3022208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	10:17 (24 HR)
Collection date and time (derived)	02 MAR 2021 10:17

US3022208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022208

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:49:49

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"/>

US3022208

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:49:49

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Visit	Was Saliva Collected?	Date of Collection
Day 3	No	
Day 5	No	
Day 7	No	
Day 9	No	
Day 14	No	
Day 21	No	
Day 28	Yes	19 OCT 2020

US3022208

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3022208

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

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.

US3022208

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:49:49

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

Yes ☐

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 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	SICKD28

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 OCT 2020
Time of assessment (00:00-23:59)	14:50 (24 HR)
Vital Signs Date and Time (derived)	19 OCT 2020 14:50
Height (xxx.x)	174 cm
Weight (xxx.x)	98.4 kg
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 OCT 2020

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

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

19 OCT 2020

US3022208

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

Visit date (dd MMM yyyy)	22 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3022208

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:19:41

Generated On: 09 Jun 2021 14:49:49

Date of updated informed consent (<i>dd MMM yyyy</i>)	22 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	22 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3022208

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

US3022208

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	10:35 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 10:35
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3022208

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 JAN 2021
Time of assessment (00:00-23:59)	11:41 (24 HR)
Vital Signs Date and Time (derived)	22 JAN 2021 11:41
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3022208

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

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 JAN 2021

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

US3022208

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

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 22 JAN 2021

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

Treatment Date and Time (derived) 22 JAN 2021 11:11

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

US3022208

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

09:15 (24 HR)

Collection date and time (derived)

22 JAN 2021 09:15

US3022208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	09:38
Collection Date and Time (derived)	22 JAN 2021 09:38

US3022208

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

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 24 Feb 2021 00:08:37

Generated On: 09 Jun 2021 14:49:49

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	23 FEB 2021
Time of assessment (<i>00:00-23:59</i>)	10:13 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:13
Temperature (<i>xxx.x</i>)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	79 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	88 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 24 Feb 2021 00:08:37

Generated On: 09 Jun 2021 14:49:49

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)	23 FEB 2021
Time of assessment (00:00-23:59)	10:13 (24 HR)
Vital Signs Date and Time (derived)	23 FEB 2021 10:13
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 24 Feb 2021 00:08:37

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Feb 2021 00:08:37

Generated On: 09 Jun 2021 14:49:49

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3022208

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 24 Feb 2021 00:08:37

Generated On: 09 Jun 2021 14:49:49

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

SUBJECT RECEIVED MODERNA ON FIRST DOSE AND WILL NOT RECEIVE ANYMORE

What was the study treatment? _____

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

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

Treatment Date and Time (derived) _____

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

What was the frequency of the study treatment dosing? _____

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

US3022208

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

10:36 (24 HR)

Collection date and time (derived)

23 FEB 2021 10:36

US3022208

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:08:37

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

26 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022208

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

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

Folder OID _____

US3022208

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

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.

US3022208

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3022208

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

AEID	USA-US051-2020-MRNA-1273-P30 1000003
Adverse event	CONGESTIVE HEART FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Start date (dd MMM yyyy)	07 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)	14 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	14 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	UPDATED SAE WITH MEDIAL RECORDS HAVE BEEN EMAILED OVER. MEDICATION AND PROCEDURE. SAE DUE TO COCAINE ABUSE.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	
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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

AEID	USA-US051-2020-MRNA-1273-P30 1000003
Adverse event	COCAINE ABUSE
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)	10 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)	10 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	10 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	14 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Mar 2021 23:00:51

Generated On: 09 Jun 2021 14:49:49

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

Yes ☒

No ☐

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT THE INJECTION SITE/
UNDERARM SWELLING

Dose per administration 500

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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US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC PAIN

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	UN UNK 2014	
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"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication POLYETHYLENE GLYCOL

Prophylaxis Yes ☐
No ☒

Indication CHRONIC CONSTIPTION

Dose per administration 17

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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US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

	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 2014	
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"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication ANASTROZOLE

Prophylaxis Yes ☒
No ☐

Indication BREAST CANCER

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

	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 2014	
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"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	UN	JUL 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"/>

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication FUROSEMIDE

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication CONGESTIVE HEART FAILURE

Dose per administration 40

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

If dose unit is Other, specify MEQ

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) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication CHRONIC GENERALIZED PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 13 Apr 2021 22:19:40

Generated On: 09 Jun 2021 14:49:49

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

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 18:29:41

Generated On: 09 Jun 2021 14:49:49

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 SEP 2020	ELECTROCARDIOGRAM	Adverse Event	
11 SEP 2020	ECHOCARDIOGRAM	Adverse Event	

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

Date of dosing discontinuation (dd MMM yyyy)	10 SEP 2020
--	-------------

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

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

US3022208

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:49:49

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 ☐

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	15/SEP/2020 10:34
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

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	05/OCT/2020 09:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/OCT/2020 16:47
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	11/NOV/2020 20:16
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

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	16/NOV/2020 08:45
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

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	23/NOV/2020 19:13
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	04/DEC/2020 13:43
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

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	08/DEC/2020 14:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Data signed: (b) (4) 23 Feb 2021 18:29:42

Generated On: 09 Jun 2021 14:49:49

SAEID	USA-US051-2020-MRNA-1273-P301000003
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	9
Date of submission (Pre-filled from custom function)	03/FEB/2021 14:41
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

Audit

US3022208 (Prod: Meridian Clinical Research-Savannah)

US3022208

Form: Participant Creation

Generated On: 09 Jun 2021 14:49:49

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'US3022208'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:19:42

US3022208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 20:01:52
	(b) (4)	

US3022208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 18:19:43
	ENDPOINT (b) (4)	

US3022208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	20 Aug 2020 20:01:52
	(b) (4)	

US3022208

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'SCRN'	(b) (4), (b) (6) System	20 Aug 2020 20:01:52

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered (b) (6) 1960'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:19:44

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '60'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'YEARS'	(b) (4), (b) (6) System	20 Aug 2020 20:02:27

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '60'	(b) (4), (b) (6) System	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Female (F)'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:49:49

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:02:27
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '20 Aug 2020'	Shanice Bennett (b) (4)	20 Aug 2020 19:41:36
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Aug 2020'	(b) (4), (b) (6) System	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2020'	(b) (4), (b) (6) System	20 Aug 2020 19:41:36

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Amendment 2 (2)'	Shanice Bennett (b) (4)	20 Aug 2020 19:41:36
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 19:41:36
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 19:41:36
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 19:41:36
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Aug 2020 19:41:36
	(b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	RWS_ENDPOINT	20 Aug 2020 18:19:43
	ENDPOINT (b) (4)	

US3022208

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:49:49

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'I'	(b) (4), (b) (6) System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 19:41:53
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:49:49

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Jan 2021 16:53:07
	(b) (4), (b) (6)	
User closed query 'Please add the medical history per source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 16:53:06
	(b) (4), (b) (6)	
Query 'Please add the medical history per source. Thank you.' answered with 'ADDED' (Site from CRA).	Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 21:54:35
User opened query 'Please add the medical history per source. Thank you.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:24:24
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:03:15

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:05:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 20:05:24
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 20:04:20
User entered 'post menopausal'	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2016'	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:03:36
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2016'	(b) (4), (b) (6) System	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2016'	(b) (4), (b) (6) System	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 20:03:36

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
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 for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:18:09
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 for no medical treatment. ' answered with 'no meds taken' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 15:51:57
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 for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 00:02:05
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)	10 Nov 2020 20:17:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:43
Data point term sent to Coder	System	10 Nov 2020 20:16:29
User entered 'hypertension'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2010'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:30
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:30
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:15:30
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:30
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2010'	(b) (4), (b) (6) System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2010'	(b) (4), (b) (6) System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:15:30

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Hepatitis C, LLT: Hepatitis C - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:42
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:42
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 20:16:29
User entered 'Hepatitis C'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:15:49
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:15:49

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLTGT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:41
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 20:16:28
User entered 'Insomnia'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 1975'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:03
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1975'	(b) (4), (b) (6) System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1975'	(b) (4), (b) (6) System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:16:03

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
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 for no medical treatment. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 13:21:50
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 for no medical treatment. ' answered with 'no meds' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 15:52:10
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 for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 00:02:32
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar disorder, LLT: Bipolar disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:32:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Nov 2020 20:32:40
Data point term sent to Coder	System	10 Nov 2020 20:16:30
User entered 'bipolar disorder'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 1975'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:16:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1975'	(b) (4), (b) (6) System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1975'	(b) (4), (b) (6) System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:16:22

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Breast neoplasms malignant and unspecified (incl nipple), HLT: Breast and nipple neoplasms malignant, PT: Breast cancer, LLT: Breast cancer - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:29
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:48:29
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 20:17:31
User entered 'breast cancer'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:39

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Breast therapeutic procedures, HLT: Mastectomies, PT: Mastectomy, LLT: Mastectomy - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:53:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Nov 2020 05:53:45
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 20:17:32
User entered 'masectomy'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:59
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:59
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:59
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:59
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:59
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:16:59
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:16:59

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLGTT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:46
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Nov 2020 20:17:46
	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 20:17:33
User entered 'depression'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 1975'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:11
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1975'	(b) (4), (b) (6) System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1975'	(b) (4), (b) (6) System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:17:11

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 13:16:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Jan 2021 13:16:39
User closed query 'Per CDM CR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 08:07:44
Data point term sent to Coder	System	06 Jan 2021 15:54:18
Query 'Per CDM CR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 15:53:50
Coding entries removed.	(b) (4), (b) (6)	06 Jan 2021 15:53:25
User entered 'CHRONIC PAIN generalized' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 15:53:25
User opened query 'Per CDM CR: Please update the condition to include the type and/or location of Pain (arms, Legs, Generalized, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 00:18:06
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: Chronic pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 20:17:45

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	10 Nov 2020 20:17:45
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	10 Nov 2020 20:17:32
User entered 'chronic Pain'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:22
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:17:22

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Constipation, LLT: Constipation chronic - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	11 Nov 2020 05:01:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Nov 2020 05:01:46
Data point term sent to Coder	System	10 Nov 2020 20:18:35
User entered 'chronic constipation'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2014'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:17:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	10 Nov 2020 20:17:39
	(b) (4)	

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2014'	(b) (4), (b) (6) System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2014'	(b) (4), (b) (6) System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 20:17:39

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Mar 2021 21:31:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Mar 2021 21:31:39
Data point term sent to Coder	System	01 Mar 2021 14:42:09
User entered 'morphine sulfate allergy'	(b) (4), (b) (6)	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 1980'	(b) (4), (b) (6)	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1980'	(b) (4), (b) (6) System	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1980'	(b) (4), (b) (6) System	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 14:41:20

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:42:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:42:50
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 14:42:09
User entered 'small bowel obstruction'	(b) (4), (b) (6)	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2015'	(b) (4), (b) (6) System	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2015'	(b) (4), (b) (6) System	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 14:41:49

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Abdominal therapeutic procedures NEC, PT: Abdominal operation, LLT: Abdominal operation - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:43:50
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:43:50
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 14:43:10
User entered 'abdominal surgery'	(b) (4), (b) (6)	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 2015'	(b) (4), (b) (6)	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'un UNK 2015'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2015'	(b) (4), (b) (6) System	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2015'	(b) (4), (b) (6) System	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 2015'	(b) (4), (b) (6) System	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '2015'	(b) (4), (b) (6) System	01 Mar 2021 14:42:11

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	01 Mar 2021 14:59:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:59:50
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:43:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:43:51
Data point term sent to Coder	System	01 Mar 2021 14:43:10
User entered 'appendectomy'	(b) (4), (b) (6)	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 1965'	(b) (4), (b) (6)	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 1965'	(b) (4), (b) (6)	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1965'	(b) (4), (b) (6) System	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1965'	(b) (4), (b) (6) System	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1965'	(b) (4), (b) (6) System	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1965'	(b) (4), (b) (6) System	01 Mar 2021 14:42:27

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:43:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:43:51
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 14:43:10
User entered 'tonsillectomy'	(b) (4), (b) (6)	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 1975'	(b) (4), (b) (6)	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 1975'	(b) (4), (b) (6)	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1975'	(b) (4), (b) (6) System	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1975'	(b) (4), (b) (6) System	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1975'	(b) (4), (b) (6) System	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1975'	(b) (4), (b) (6) System	01 Mar 2021 14:43:07

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Drug allergy - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:45:11
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	01 Mar 2021 14:45:11
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 14:44:11
User entered 'codeine allergy'	(b) (4), (b) (6)	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'un UNK 1980'	(b) (4), (b) (6)	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'Jan 1980'	(b) (4), (b) (6) System	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '1980'	(b) (4), (b) (6) System	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered empty.	(b) (4), (b) (6) System	01 Mar 2021 14:43:21

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '14:15'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered '20 Aug 2020 14:15'	(b) (4), (b) (6) System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '174' cm	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '97.0' kg	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
Amendment Manager: User entered '32.03858'	(b) (4), (b) (6)	
User entered '32.0'	System	17 Sep 2020 00:16:37
DataPoint set to visible.	System	20 Aug 2020 20:04:46
	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	20 Aug 2020 20:04:46
DataPoint set to visible.	System	20 Aug 2020 19:41:53

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 05:34:31
Query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:37:53
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:49:23
User entered '36.8' C	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '96'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '12'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '130'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:37:46
User entered '86'	Stella Yoon (b) (4)	20 Aug 2020 20:04:46
	(b) (4)	

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 20:04:46

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:32:27

US3022208

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:32:27

US3022208

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 20:04:53
	(b) (4)	

US3022208

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 20:04:53
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2016'	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:49:49

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:05:10
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4)	
	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

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)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:49:49

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:32:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'lives in a community with ongoing person to person transmission'	Stella Yoon (b) (4)	20 Aug 2020 20:06:07
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per GCL Lab Reconciliation Requery2 : Saliva: Thank you for initiating the Illness visit, however please confirm to update the 19Oct2020 sample in the Saliva collection form.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Dec 2020 03:09:21
Query 'Per GCL Lab Reconciliation Requery2 : Saliva: Thank you for initiating the Illness visit, however please confirm to update the 19Oct2020 sample in the Saliva collection form.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:34:02
User opened query 'Per GCL Lab Reconciliation Requery2 : Saliva: Thank you for initiating the Illness visit, however please confirm to update the 19Oct2020 sample in the Saliva collection form.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:22:22
User closed query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for your response, however please confirm in the response if a Saliva Sample dated 19OCT2020 was collected for the subject and sent to PPD Central lab as the above dated sample is reported under Convalescence Visit Day 28 in PPD If yes then update the data in the Saliva log or Covid diagnostic form as applicable.. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 13:22:22
Query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for your response, however please confirm in the response if a Saliva Sample dated 19OCT2020 was collected for the subject and sent to PPD Central lab as the above dated sample is reported under Convalescence Visit Day 28 in PPD If yes then update the data in the Saliva log or Covid diagnostic form as applicable.. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:50

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation Requery: Saliva: Thank you for your response, however please confirm in the response if a Saliva Sample dated 19OCT2020 was collected for the subject and sent to PPD Central lab as the above dated sample is reported under Convalescence Visit Day 28 in PPD If yes then update the data in the Saliva log or Covid diagnostic form as applicable.. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:35:53
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 07:35:53
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'subject tested positive outside of clinic ' (Site from DM).	(b) (4), (b) (6)	13 Nov 2020 23:26:40
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Oct 2020 06:29:37
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Clinic (Clinic)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'VISIT1'	(b) (4), (b) (6) System	20 Aug 2020 20:06:20

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:59:28

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 05:57:49
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:57:49
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 18:59:28
User entered '106521' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:59:28

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 18:59:28

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

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)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

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)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:06:33

US3022208

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:49:49

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:28:43
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 19:11:09
User entered 'No (N)'	Morgan Deal (b) (4)	12 Nov 2020 19:11:04
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 17:22:08
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:16
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:48:33

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:38:08
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:51:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User entered '174' cm	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User entered '97.0' kg	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:38:08
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:51:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User entered '174' cm	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User entered '97.0' kg	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14:15'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered '20 Aug 2020 14:15'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '36.8' C	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (Oral)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '96'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '12'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '130'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '86'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 06:38:08
Query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	12 Nov 2020 17:51:33
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:19:16
User entered '174' cm	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 17:51:24
User entered '97.0' kg	Stella Yoon (b) (4)	20 Aug 2020 20:07:55
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:29:45
User closed query 'Data is required. Please provide.' (Site from System).	System	24 Aug 2020 16:13:10
Query 'Data is required. Please provide.' answered by System data change (Site from System).		24 Aug 2020 16:13:10
User entered '15:50' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	24 Aug 2020 16:13:10
User opened query 'Data is required. Please provide.' (Site from System).	System	20 Aug 2020 20:07:55
User entered empty.	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User entered '20 Aug 2020 15:50'	System	24 Aug 2020 16:13:10
User entered empty.	System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '36.6' C	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (Oral)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '103'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '133'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '88'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 20:07:55

US3022208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:40

US3022208

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:40

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 19:43:38
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

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)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 19:43:38
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '20 Aug 2020'	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 19:43:38
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '15:13'	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered '20 Aug 2020 15:13'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'ONCE'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:55:30
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'date 20aug2020 is correct date' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 23:49:53
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 20AUG2020 is recorded under Visit1 Day1 visit in EDC, however the same is reported under Visit 1 Day1 Visit with date 21AUG2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:47:24
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14:37'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered '20 Aug 2020 14:37'	(b) (4), (b) (6) System	20 Aug 2020 20:08:58

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:49:49

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 07:01:46
Query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' answered with '20aug2020 date is correct' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 23:45:20
User opened query 'Per GCL Lab Rec: it appears GCL has this as 21AUG2020 Please confirm the date of 20AUG2020 is for Day 1 or clarify' (Site from DM).	(b) (4), (b) (6)	18 Oct 2020 18:05:33
User entered '20 Aug 2020'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Stella Yoon (b) (4)	20 Aug 2020 20:09:10
	(b) (4)	

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14:49'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered '20 Aug 2020 14:49'	(b) (4), (b) (6) System	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 20:09:10

US3022208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 20:09:14

US3022208

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered '1'	(b) (4), (b) (6) System	20 Aug 2020 20:09:14

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:17', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	System	20 Aug 2020 19:46:51
User entered 'Yes (Y)'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:27', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6' User entered '97.9'	System	20 Aug 2020 19:46:51
	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '99d18617-fb89-493e-a722-64649ad6a6a6'	(b) (4), (b) (6) System	20 Aug 2020 19:46:51
User entered '20 Aug 2020 15:46'	System	20 Aug 2020 19:46:51

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 15:33'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 18:03'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:48:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	(b) (4), (b) (6)	
	System	21 Aug 2020 00:49:11
User entered 'Yes (Y)'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:48:50', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	(b) (4), (b) (6)	
User entered '97.3'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:48:58', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	(b) (4), (b) (6) System	21 Aug 2020 00:49:11
User entered 'No (N)'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '9c78286a-2f5f-44f8-ab7e-dc754081aa9c'	(b) (4), (b) (6) System	21 Aug 2020 00:49:11
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 00:49:11

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 18:58'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 2'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:17:36', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:18:21
User entered 'No (N)'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:17:59', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:18:21
User entered 'Yes (Y)'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'UPDATED' (Site from System).	(b) (4), (b) (6)	28 Aug 2020 04:19:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:13', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:06
User entered '1'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:13', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	(b) (4), (b) (6) System	22 Aug 2020 00:18:21
User entered '0'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '929070d5-a993-4b94-9845-ac12e7948b27'	(b) (4), (b) (6) System	22 Aug 2020 00:18:21
User entered '21 Aug 2020 20:18'	System	22 Aug 2020 00:18:21

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 3'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 4'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:20:44
User entered 'Yes (Y)'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78' User entered '97.3'	System	23 Aug 2020 17:20:44
	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:36', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:20:44
User entered 'No (N)'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '618a4611-0923-45a9-9b70-ba697a3d2b78'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:20:44
User entered '23 Aug 2020 13:20'	System	23 Aug 2020 17:20:44

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 5'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 6'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:28', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '48528472-4c23-4401-bb58-29a8f58bb5e4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 16:02:13

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '48528472-4c23-4401-bb58-29a8f58bb5e4'	(b) (4), (b) (6)	
	System	25 Aug 2020 16:02:13
User entered 'No (N)'	System	25 Aug 2020 16:02:13

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:46', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '48528472-4c23-4401-bb58-29a8f58bb5e4'	(b) (4), (b) (6)	
	System	25 Aug 2020 16:02:13
User entered '25 Aug 2020 12:01'	System	25 Aug 2020 16:02:13

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 7'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:05', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '950060cf-3c29-4aeb-a3af-3a01dcf8c09a'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 00:09:15

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '950060cf-3c29-4aeb-a3af-3a01dcf8c09a'	(b) (4), (b) (6) System	27 Aug 2020 00:09:15
User entered 'No (N)'	System	27 Aug 2020 00:09:15

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:12', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '950060cf-3c29-4aeb-a3af-3a01dcf8c09a'	(b) (4), (b) (6) System	27 Aug 2020 00:09:15
User entered '26 Aug 2020 20:09'	System	27 Aug 2020 00:09:15

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:46:58', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	(b) (4), (b) (6) System	20 Aug 2020 19:47:17
User entered 'None (1)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:01', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	(b) (4), (b) (6)	
	System	20 Aug 2020 19:47:17
User entered 'No (N)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:04', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	(b) (4), (b) (6) System	20 Aug 2020 19:47:17
User entered 'No (N)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	(b) (4), (b) (6) System	20 Aug 2020 19:47:17
User entered 'None (1)'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:12', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'f98b8385-08bc-4c04-83f3-4ac2d3e74269'	(b) (4), (b) (6) System	20 Aug 2020 19:47:17
User entered '20 Aug 2020 15:47'	System	20 Aug 2020 19:47:17

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 15:33'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 18:03'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:16', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	(b) (4), (b) (6) System	21 Aug 2020 00:49:33
User entered 'None (1)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:20', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:23', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	(b) (4), (b) (6) System	21 Aug 2020 00:49:33
User entered 'No (N)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:27', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	(b) (4), (b) (6) System	21 Aug 2020 00:49:33
User entered 'None (1)'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5f75e82d-b1e7-49b6-b875-301924bcd8a6'	(b) (4), (b) (6) System	21 Aug 2020 00:49:33
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 00:49:33

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 18:58'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 2'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' canceled (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:10:22
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 09:22:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:37', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	System	22 Aug 2020 00:19:37
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:18:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:19:37
User entered 'Yes (Y)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:01', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6) System	22 Aug 2020 00:19:37
User entered '1'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:07', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:19:37
User entered 'Yes (Y)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:19', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6) System	22 Aug 2020 00:19:37
User entered '1'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 15:42:12
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' answered with 'will add med ' (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 21:17:28
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:11:51
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' canceled (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 12:06:36

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Pain at Injection Site and Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify.' (Site from DM). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6)	09 Sep 2020 09:23:57
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with some activity (3)'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '137fc4f8-1595-4b49-b3e8-1d8d298a23f3'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:19:37
User entered '21 Aug 2020 20:19'	System	22 Aug 2020 00:19:37

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 3'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

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) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

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) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 4'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:08
User entered 'Does not interfere with activity (2)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	(b) (4), (b) (6)	
User entered 'No (N)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:20:57', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:08
User entered 'No (N)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:01', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	(b) (4), (b) (6)	23 Aug 2020 17:21:08
User entered 'None (1)'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:04', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '72d89327-2d92-451b-8ad5-935aa50fb9d4'	(b) (4), (b) (6)	
User entered '23 Aug 2020 13:21'	System	23 Aug 2020 17:21:08

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 5'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

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) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

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) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 6'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:55', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	(b) (4), (b) (6)	
	System	25 Aug 2020 16:03:13
User entered 'None (1)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:01:59', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	(b) (4), (b) (6)	
User entered 'No (N)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:17', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	(b) (4), (b) (6) System	25 Aug 2020 16:03:13
User entered 'No (N)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:29', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	(b) (4), (b) (6)	
	System	25 Aug 2020 16:03:13
User entered 'None (1)'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5dbda000-515f-45ce-89a9-f6403eec8af6'	(b) (4), (b) (6)	
	System	25 Aug 2020 16:03:13
User entered '25 Aug 2020 12:02'	System	25 Aug 2020 16:03:13

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 7'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	(b) (4), (b) (6) System	27 Aug 2020 00:09:34
User entered 'None (1)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:23', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	(b) (4), (b) (6) System	27 Aug 2020 00:09:34
User entered 'No (N)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:26', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	(b) (4), (b) (6) System	27 Aug 2020 00:09:34
User entered 'None (1)'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:29', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '67d40273-0402-4042-8c35-8cc118c240e5'	(b) (4), (b) (6)	
User entered '26 Aug 2020 20:09'	System	27 Aug 2020 00:09:34

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:22', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:35', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:47:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:17', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
	System	20 Aug 2020 19:48:37
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered 'None (0)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:28', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T15:48:32', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e2577d39-1cf2-410d-89aa-3a868305fbb2'	(b) (4), (b) (6)	
User entered '20 Aug 2020 15:48'	System	20 Aug 2020 19:48:37

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 15:33'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 18:03'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:37', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:42', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6)	
User entered 'None (0)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6) System	21 Aug 2020 00:49:56
User entered 'No (N)'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-20T20:49:52', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'fed61a0c-e7c9-4c6e-a17f-5f3f10ec8ae5'	(b) (4), (b) (6) System	21 Aug 2020 00:49:56
User entered '20 Aug 2020 20:49'	System	21 Aug 2020 00:49:56

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '20 Aug 2020 18:58'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered 'Day 2'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:40', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:45', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:20:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:20:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:19:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:20:16
User entered 'No interference with activity (1)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:02', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:20:16
User entered 'Some interference with activity or >2 episodes/24 hours (2)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:07', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
User entered 'None (0)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:11', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6) System	22 Aug 2020 00:20:16
User entered 'No (N)'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-21T20:20:14', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'c4eb0d32-920b-417a-87d1-eba426357b89'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:20:16
User entered '21 Aug 2020 20:20'	System	22 Aug 2020 00:20:16

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 3'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

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) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 4'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:15', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:50
User entered 'No interference with activity (1)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:20', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:50
User entered 'No interference with activity (1)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:26', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:50
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:50
User entered 'Some interference with activity (2)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:33', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	System	23 Aug 2020 17:21:50
User entered 'None (0)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:36', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
User entered 'None (0)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:41', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:50
User entered 'No (N)'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-23T13:21:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'e6228013-c12a-4dcf-804f-3c882271dd11'	(b) (4), (b) (6)	
	System	23 Aug 2020 17:21:50
User entered '23 Aug 2020 13:21'	System	23 Aug 2020 17:21:50

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 5'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

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) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:59:00

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 6'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:48', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:50', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:55', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:02:58', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:03:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
User entered 'None (0)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:03:03', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6) System	25 Aug 2020 16:03:44
User entered 'No (N)'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-25T12:03:06', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'd5a57cb2-80ee-4c06-802b-9a9bfe01f38b'	(b) (4), (b) (6)	
	System	25 Aug 2020 16:03:44
User entered '25 Aug 2020 12:03'	System	25 Aug 2020 16:03:44

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 7'	System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:35', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:39', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:41', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:44', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'None (0)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:52', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered 'No (N)'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-08-26T20:09:55', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '0438156d-a71c-4548-b450-28a0a47c0207'	(b) (4), (b) (6)	
User entered '26 Aug 2020 20:09'	System	27 Aug 2020 00:09:59

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:49:49

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:19:11
User entered '27 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 17:03:46
Query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'this is correct ' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 17:02:31
User opened query 'Safety Call Day 8 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Oct 2020 17:01:53
User entered '03 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:53

US3022208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:01:58

US3022208

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered 'I'	(b) (4), (b) (6) System	15 Oct 2020 17:01:58

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:03:59

US3022208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Oct 2020 17:04:04

US3022208

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 07:57:24
User entered '1'	(b) (4), (b) (6) System	15 Oct 2020 17:04:04

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:34:26
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'no illness visit needed due to no symptoms' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 23:30:27
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: sample dated 19 OCT 2020 is reported under illness Visit Day 1 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 11:37:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 16:19:40
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	(b) (4), (b) (6)	15 Oct 2020 17:04:34
answered with 'this is correct ' (Site from System).		
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	15 Oct 2020 17:04:13
User entered '14 Sep 2020'	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 17:04:13

US3022208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:41:40
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Oct 2020 17:06:33

US3022208

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 06:41:40
User entered 'I'	System	15 Oct 2020 17:06:33

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03DEC2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM). Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03DEC2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 07:52:34
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 03DEC2020 is reported under Visit 3 Day 57 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under Visit 3 Day 57 Visit on Immunogenicity Assessment page.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 19:51:00
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 10:25:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' answered with 'UDATED' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 03:09:46
	(b) (4), (b) (6)	03 Dec 2020 18:34:13

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19OCT2020 is reported under Convalescence Visit Day 28 in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). User entered 'No (N)'	(b) (4), (b) (6) (b) (4)	03 Dec 2020 03:49:26
	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'VISIT2'	(b) (4), (b) (6) System	10 Nov 2020 22:42:29

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Shanice Bennett (b) (4)	10 Nov 2020 22:42:35
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:35

US3022208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:39

US3022208

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:39

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM, re-query: Response "THE SUBJECT WAS DISCONTINUED DUE TO AN SAE WHICH IS UPDATED ON THE DISPOSITION PAGE" is noted. However, on this page reason not given = Confirmed COVID-19 which is not matching the reason on Dosing Discontinuation form. Kindly review and update as appropriate, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	04 Dec 2020 11:57:44
Query 'Per CDM, re-query: Response "THE SUBJECT WAS DISCONTINUED DUE TO AN SAE WHICH IS UPDATED ON THE DISPOSITION PAGE" is noted. However, on this page reason not given = Confirmed COVID-19 which is not matching the reason on Dosing Discontinuation form. Kindly review and update as appropriate, else clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 20:08:09
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 20:08:03
User opened query 'Per CDM, re-query: Response "THE SUBJECT WAS DISCONTINUED DUE TO AN SAE WHICH IS UPDATED ON THE DISPOSITION PAGE" is noted. However, on this page reason not given = Confirmed COVID-19 which is not matching the reason on Dosing Discontinuation form. Kindly review and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:46:06
Query 'Per CDM (requery): Response is noted. However, the subject has been confirmed COVID-19. According to eCCGs (page 39), please update the "primary reason of dosing discontinuation" to "Due to SARS-COV-2" and appropriate details on dosing discontinuation form, else clarify. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 08:40:10

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

If No, reason not given

Audit	User	Time (GMT)
User opened query 'Per CDM (requery): Response is noted. However, the subject has been confirmed COVID-19. According to eCCGs (page 39), please update the "primary reason of dosing discontinuation" to "Due to SARS-COV-2" and appropriate details on dosing discontinuation form, else clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:02:02
User closed query 'Per CDM: Please review this field and reconcile with the Dosing Discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 08:02:02
Query 'Per CDM: Please review this field and reconcile with the Dosing Discontinuation form as appropriate. Thank you.' answered with 'THE SUBJECT WAS DISCONTINUED DUE TO AN SAE WHICH IS UPDATED ON THE DISPOSITION PAGE.' (Site from DM).	Morgan Deal (b) (4)	25 Nov 2020 20:22:03
User opened query 'Per CDM: Please review this field and reconcile with the Dosing Discontinuation form as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:49:57
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).		13 Nov 2020 23:02:13
User entered 'Confirmed COVID-19 (COVID)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	13 Nov 2020 23:02:13
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	
User entered empty.	System	10 Nov 2020 22:42:44
	Shanice Bennett (b) (4)	10 Nov 2020 22:42:44
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'sae' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 20:08:03
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 22:42:44
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:42:44

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 22:43:11
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:43:11

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 22:43:22
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered empty.	(b) (4), (b) (6) System	10 Nov 2020 22:43:22

US3022208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 22:44:18
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	10 Nov 2020 22:44:11
	(b) (4)	

US3022208

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User entered '1'	System	10 Nov 2020 22:44:18
User entered empty.	System	10 Nov 2020 22:44:11

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:38

US3022208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:44:42

US3022208

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'I'	(b) (4), (b) (6) System	10 Nov 2020 22:44:42

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:45:33

US3022208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:19

US3022208

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'I'	(b) (4), (b) (6) System	10 Nov 2020 22:47:19

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:29

US3022208

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4)	10 Nov 2020 22:47:29
	(b) (4)	

US3022208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 22:47:33

US3022208

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'I'	(b) (4), (b) (6) System	10 Nov 2020 22:47:33

US3022208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:02

US3022208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:02

US3022208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:02

US3022208

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'VISIT3'	(b) (4), (b) (6) System	15 Dec 2020 19:49:02

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '03 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '10:17'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered '03 Dec 2020 10:17'	(b) (4), (b) (6) System	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '89'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'bpm'	(b) (4), (b) (6) System	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '15'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'breaths/min'	(b) (4), (b) (6) System	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '99'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'mmHg'	(b) (4), (b) (6) System	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '70'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'mmHg'	(b) (4), (b) (6) System	15 Dec 2020 19:49:21

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	

US3022208

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	

US3022208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:32

US3022208

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '03 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 19:49:32

US3022208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:59

US3022208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '03 Dec 2020'	(b) (4), (b) (6)	15 Dec 2020 19:49:59

US3022208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '10:32'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:49:59

US3022208

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered '03 Dec 2020 10:32'	(b) (4), (b) (6) System	15 Dec 2020 19:49:59

US3022208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:50:09

US3022208

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered '1'	(b) (4), (b) (6) System	15 Dec 2020 19:50:09

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 64'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-21T16:08:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ff3fdd77-b0c7-4349-8879-0c8d6a60483f'	(b) (4), (b) (6)	21 Oct 2020 20:08:39
User entered 'No (N)'	System	21 Oct 2020 20:08:39

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-21T16:08:29', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ff3fdd77-b0c7-4349-8879-0c8d6a60483f'	(b) (4), (b) (6)	21 Oct 2020 20:08:39
User entered 'No (N)'	System	21 Oct 2020 20:08:39

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-21T16:08:35', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ff3fdd77-b0c7-4349-8879-0c8d6a60483f' User entered '21 Oct 2020 16:08:35'	(b) (4), (b) (6) System	21 Oct 2020 20:08:39
	System	21 Oct 2020 20:08:39

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 71'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-27T20:23:30', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5d404749-42b9-4351-ae1b-85aee5af345d'	(b) (4), (b) (6)	28 Oct 2020 00:23:40
User entered 'No (N)'	System	28 Oct 2020 00:23:40

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-27T20:23:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5d404749-42b9-4351-ae1b-85aee5af345d'	(b) (4), (b) (6)	28 Oct 2020 00:23:40
User entered 'No (N)'	System	28 Oct 2020 00:23:40

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-10-27T20:23:38', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5d404749-42b9-4351-ae1b-85aee5af345d'	(b) (4), (b) (6)	
	System	28 Oct 2020 00:23:40
User entered '27 Oct 2020 20:23:38'	System	28 Oct 2020 00:23:40

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:59:00
Data entry locked.	(b) (4), (b) (6)	
	System	20 Aug 2020 19:43:38
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 78'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Please 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Please 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Please 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50
Data entry locked.	System	20 Aug 2020 19:43:38
User entered 'Day 92'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Please 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Please 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Please 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 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 19:43:38

US3022208

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:00:50
Data entry locked.	System	20 Aug 2020 19:43:38
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 19:43:38

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2020-12-01T16:09:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '70a5c420-c0ba-4e70-b029-1c337c195b36'	System	01 Dec 2020 21:09:43
User entered 'No (N)'	System	01 Dec 2020 21:09:43

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2020-12-01T16:09:34', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '70a5c420-c0ba-4e70-b029-1c337c195b36'	System	01 Dec 2020 21:09:43
User entered 'No (N)'	System	01 Dec 2020 21:09:43

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-12-01T16:09:39', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '70a5c420-c0ba-4e70-b029-1c337c195b36'	System	01 Dec 2020 21:09:43
User entered '01 Dec 2020 16:09:39'	System	01 Dec 2020 21:09:43

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2020-12-05T13:03:41', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '726fc756-b5a0-410c-9e64-59c942874ac5'	System	05 Dec 2020 18:05:01
User entered 'Yes (Y)'	System	05 Dec 2020 18:05:01

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2020-12-05T13:03:52', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '726fc756-b5a0-410c-9e64-59c942874ac5'	System	05 Dec 2020 18:05:01
User entered 'Yes (Y)'	System	05 Dec 2020 18:05:01

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-12-05T13:04:21', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '726fc756-b5a0-410c-9e64-59c942874ac5'	System	05 Dec 2020 18:05:01
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 18:05:01

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2020-12-05T13:04:27', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '726fc756-b5a0-410c-9e64-59c942874ac5'	System	05 Dec 2020 18:05:01
User entered 'No (N)'	System	05 Dec 2020 18:05:01

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2020-12-05T13:04:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '726fc756-b5a0-410c-9e64-59c942874ac5'	System	05 Dec 2020 18:05:01
User entered 'No (N)'	System	05 Dec 2020 18:05:01

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-12-05T13:04:52', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '726fc756-b5a0-410c-9e64-59c942874ac5'	System	05 Dec 2020 18:05:01
User entered '05 Dec 2020 13:04:52'	System	05 Dec 2020 18:05:01

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2020-12-14T15:27:08', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a0717ed7-717b-415b-8f40-384387445b30'	System	14 Dec 2020 20:27:19
User entered 'No (N)'	System	14 Dec 2020 20:27:19

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2020-12-14T15:27:10', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a0717ed7-717b-415b-8f40-384387445b30'	System	14 Dec 2020 20:27:19
User entered 'No (N)'	System	14 Dec 2020 20:27:19

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-12-14T15:27:15', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a0717ed7-717b-415b-8f40-384387445b30'	System	14 Dec 2020 20:27:19
User entered '14 Dec 2020 15:27:15'	System	14 Dec 2020 20:27:19

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2020-12-28T12:16:22', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '92de39ed-7dbf-4b93-b190-3d27b21d2da0'	System	29 Dec 2020 13:12:12
User entered 'No (N)'	System	29 Dec 2020 13:12:12

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2020-12-28T12:16:24', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '92de39ed-7dbf-4b93-b190-3d27b21d2da0'	System	29 Dec 2020 13:12:12
User entered 'No (N)'	System	29 Dec 2020 13:12:12

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2020-12-28T12:16:28', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '92de39ed-7dbf-4b93-b190-3d27b21d2da0'	System	29 Dec 2020 13:12:12
User entered '28 Dec 2020 12:16:28'	System	29 Dec 2020 13:12:12

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-02T10:08:43', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '7780ad8f-c10e-458a-8b7d-7effa0494977'	System	02 Jan 2021 15:08:52
User entered 'No (N)'	System	02 Jan 2021 15:08:52

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-01-02T10:08:46', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '7780ad8f-c10e-458a-8b7d-7effa0494977'	System	02 Jan 2021 15:08:52
User entered 'No (N)'	System	02 Jan 2021 15:08:52

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-01-02T10:08:49', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '7780ad8f-c10e-458a-8b7d-7effa0494977'	System	02 Jan 2021 15:08:52
User entered '02 Jan 2021 10:08:49'	System	02 Jan 2021 15:08:52

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-09T18:06:12', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8ffce12c-b174-41f7-80da-edb0488f38a4'	System	09 Jan 2021 23:06:25
User entered 'No (N)'	System	09 Jan 2021 23:06:25

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-01-09T18:06:18', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8ffce12c-b174-41f7-80da-edb0488f38a4'	System	09 Jan 2021 23:06:25
User entered 'No (N)'	System	09 Jan 2021 23:06:25

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-01-09T18:06:22', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8ffce12c-b174-41f7-80da-edb0488f38a4' User entered '09 Jan 2021 18:06:22'	System	09 Jan 2021 23:06:25
	System	09 Jan 2021 23:06:25

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-16T19:11:09', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ccb545bc-450a-4e9e-b94c-624c11f78405'	System	17 Jan 2021 00:11:21
User entered 'No (N)'	System	17 Jan 2021 00:11:21

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-01-16T19:11:12', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ccb545bc-450a-4e9e-b94c-624c11f78405'	System	17 Jan 2021 00:11:21
User entered 'No (N)'	System	17 Jan 2021 00:11:21

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-01-16T19:11:15', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ccb545bc-450a-4e9e-b94c-624c11f78405' User entered '16 Jan 2021 19:11:15'	System	17 Jan 2021 00:11:21

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-24T16:52:02', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'bb6d7901-6239-4158-8608-f5616361e7be'	System	24 Jan 2021 21:52:35
User entered 'Yes (Y)'	System	24 Jan 2021 21:52:35

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-01-24T16:52:13', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'bb6d7901-6239-4158-8608-f5616361e7be'	System	24 Jan 2021 21:52:35
User entered 'No (N)'	System	24 Jan 2021 21:52:35

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-24T16:52:19', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'bb6d7901-6239-4158-8608-f5616361e7be'	System	24 Jan 2021 21:52:35
User entered 'No (N)'	System	24 Jan 2021 21:52:35

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-24T16:52:27', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'bb6d7901-6239-4158-8608-f5616361e7be'	System	24 Jan 2021 21:52:35
User entered 'No (N)'	System	24 Jan 2021 21:52:35

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-01-24T16:52:31', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'bb6d7901-6239-4158-8608-f5616361e7be' User entered '24 Jan 2021 16:52:31'	System	24 Jan 2021 21:52:35

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-01-30T01:14:02', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ea3d8818-a853-44cd-8ace-e305ad33b1ee'	System	30 Jan 2021 06:14:14
User entered 'No (N)'	System	30 Jan 2021 06:14:14

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-01-30T01:14:07', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ea3d8818-a853-44cd-8ace-e305ad33b1ee'	System	30 Jan 2021 06:14:14
User entered 'No (N)'	System	30 Jan 2021 06:14:14

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-01-30T01:14:10', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ea3d8818-a853-44cd-8ace-e305ad33b1ee' User entered '30 Jan 2021 01:14:10'	System	30 Jan 2021 06:14:14
	System	30 Jan 2021 06:14:14

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-02-09T10:06:57', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5196d92d-41e3-4622-81a8-6eb3c3fbab31'	System	09 Feb 2021 15:07:11
User entered 'No (N)'	System	09 Feb 2021 15:07:11

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-02-09T10:06:59', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5196d92d-41e3-4622-81a8-6eb3c3fbab31'	System	09 Feb 2021 15:07:11
User entered 'No (N)'	System	09 Feb 2021 15:07:11

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-02-09T10:07:03', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '5196d92d-41e3-4622-81a8-6eb3c3fbab31' User entered '09 Feb 2021 10:07:03'	System	09 Feb 2021 15:07:11

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-02-22T15:44:47', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a8284a5f-ad2f-4cb1-8fae-5682306898c9'	System	22 Feb 2021 20:45:03
User entered 'No (N)'	System	22 Feb 2021 20:45:03

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-02-22T15:44:53', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a8284a5f-ad2f-4cb1-8fae-5682306898c9'	System	22 Feb 2021 20:45:03
User entered 'No (N)'	System	22 Feb 2021 20:45:03

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-02-22T15:44:57', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a8284a5f-ad2f-4cb1-8fae-5682306898c9'	System	22 Feb 2021 20:45:03
User entered '22 Feb 2021 15:44:57'	System	22 Feb 2021 20:45:03

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-02-27T10:36:02-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '46f701b2-5062-49ee-aa67-769e07dd4c47'	System	27 Feb 2021 15:36:22
User entered 'No (N)'	System	27 Feb 2021 15:36:22

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-02-27T10:36:05-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '46f701b2-5062-49ee-aa67-769e07dd4c47'	System	27 Feb 2021 15:36:22
User entered 'No (N)'	System	27 Feb 2021 15:36:22

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-02-27T10:36:10-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '46f701b2-5062-49ee-aa67-769e07dd4c47'	System	27 Feb 2021 15:36:22
User entered '27 Feb 2021 10:36:10'	System	27 Feb 2021 15:36:22

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-03-08T11:57:37-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '73e5b2f4-191f-4202-a914-2490c632f861'	System	08 Mar 2021 16:57:49
User entered 'No (N)'	System	08 Mar 2021 16:57:49

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-03-08T11:57:41-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '73e5b2f4-191f-4202-a914-2490c632f861'	System	08 Mar 2021 16:57:49
User entered 'No (N)'	System	08 Mar 2021 16:57:49

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-03-08T11:57:44-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '73e5b2f4-191f-4202-a914-2490c632f861' User entered '08 Mar 2021 11:57:44'	System	08 Mar 2021 16:57:49
	System	08 Mar 2021 16:57:49

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-03-13T04:11:43-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '80024386-818d-4a35-92f1-09aff295629d'	System	13 Mar 2021 09:11:59
User entered 'No (N)'	System	13 Mar 2021 09:11:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-03-13T04:11:47-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '80024386-818d-4a35-92f1-09aff295629d'	System	13 Mar 2021 09:11:59
User entered 'No (N)'	System	13 Mar 2021 09:11:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-03-13T04:11:53-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '80024386-818d-4a35-92f1-09aff295629d'	System	13 Mar 2021 09:11:59
User entered '13 Mar 2021 04:11:53'	System	13 Mar 2021 09:11:59

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-03-21T13:04:03-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '80404302-1e21-49ef-bc42-4bd01cd31774'	System	21 Mar 2021 17:07:03
User entered 'No (N)'	System	21 Mar 2021 17:07:03

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-03-21T13:04:05-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '80404302-1e21-49ef-bc42-4bd01cd31774'	System	21 Mar 2021 17:07:03
User entered 'No (N)'	System	21 Mar 2021 17:07:03

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-03-21T13:04:10-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '80404302-1e21-49ef-bc42-4bd01cd31774'	System	21 Mar 2021 17:07:03
User entered '21 Mar 2021 13:04:10'	System	21 Mar 2021 17:07:03

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-03-29T19:42:13-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a5d6c540-8472-4ade-a0b1-03c6be7097ab' User entered 'No (N)'	System	29 Mar 2021 23:42:49
	System	29 Mar 2021 23:42:49

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-03-29T19:42:41-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a5d6c540-8472-4ade-a0b1-03c6be7097ab'	System	29 Mar 2021 23:42:49
User entered 'No (N)'	System	29 Mar 2021 23:42:49

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-03-29T19:42:45-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'a5d6c540-8472-4ade-a0b1-03c6be7097ab' User entered '29 Mar 2021 19:42:45'	System	29 Mar 2021 23:42:49
	System	29 Mar 2021 23:42:49

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-04-03T15:55:09-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ac2fe3ec-25ea-4067-aa89-182dc4788665'	System	03 Apr 2021 19:55:18
User entered 'No (N)'	System	03 Apr 2021 19:55:18

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-04-03T15:55:11-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ac2fe3ec-25ea-4067-aa89-182dc4788665'	System	03 Apr 2021 19:55:18
User entered 'No (N)'	System	03 Apr 2021 19:55:18

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-04-03T15:55:15-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: 'ac2fe3ec-25ea-4067-aa89-182dc4788665'	System	03 Apr 2021 19:55:18
User entered '03 Apr 2021 15:55:15'	System	03 Apr 2021 19:55:18

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (055dec66dc3e364a)', Time: '2021-04-10T14:25:51-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8ae67e8a-90f3-48f3-9409-304f83e39455'	System	10 Apr 2021 18:26:05
User entered 'No (N)'	System	10 Apr 2021 18:26:05

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (055dec66dc3e364a)', Time: '2021-04-10T14:25:54-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8ae67e8a-90f3-48f3-9409-304f83e39455'	System	10 Apr 2021 18:26:05
User entered 'No (N)'	System	10 Apr 2021 18:26:05

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-04-10T14:25:58-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8ae67e8a-90f3-48f3-9409-304f83e39455'	System	10 Apr 2021 18:26:05
User entered '10 Apr 2021 14:25:58'	System	10 Apr 2021 18:26:05

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (a13dee14e9536026)', Time: '2021-04-19T06:15:24-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '2ffe3e1b-2af1-4677-bba3-08dec2a922fe' User entered 'No (N)'	System	19 Apr 2021 10:15:37
	System	19 Apr 2021 10:15:37

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Have you been exposed to someone with 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 (a13dee14e9536026)', Time: '2021-04-19T06:15:30-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '2ffe3e1b-2af1-4677-bba3-08dec2a922fe'	System	19 Apr 2021 10:15:37
User entered 'No (N)'	System	19 Apr 2021 10:15:37

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a13dee14e9536026)', Time: '2021-04-19T06:15:33-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '2ffe3e1b-2af1-4677-bba3-08dec2a922fe' User entered '19 Apr 2021 06:15:33'	System	19 Apr 2021 10:15:37
	System	19 Apr 2021 10:15:37

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (a13dee14e9536026)', Time: '2021-04-24T00:01:53-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '1a519f18-9e80-4cfd-8df6-e78ee1fbc1bb'	System	24 Apr 2021 04:05:11
User entered 'No (N)'	System	24 Apr 2021 04:05:11

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (a13dee14e9536026)', Time: '2021-04-24T00:01:57-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '1a519f18-9e80-4cfd-8df6-e78ee1fbc1bb'	System	24 Apr 2021 04:05:11
User entered 'No (N)'	System	24 Apr 2021 04:05:11

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a13dee14e9536026)', Time: '2021-04-24T00:02:03-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '1a519f18-9e80-4cfd-8df6-e78ee1fbc1bb' User entered '24 Apr 2021 00:02:03'	System	24 Apr 2021 04:05:11
	System	24 Apr 2021 04:05:11

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[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 (a13dee14e9536026)', Time: '2021-05-01T16:24:29-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8360fd8a-80a7-40d3-a7e2-5917eb4e898f'	System	01 May 2021 20:24:55
User entered 'No (N)'	System	01 May 2021 20:24:55

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

Have you been exposed to someone with 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 (a13dee14e9536026)', Time: '2021-05-01T16:24:35-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8360fd8a-80a7-40d3-a7e2-5917eb4e898f'	System	01 May 2021 20:24:55
User entered 'No (N)'	System	01 May 2021 20:24:55

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a13dee14e9536026)', Time: '2021-05-01T16:24:38-04:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '8360fd8a-80a7-40d3-a7e2-5917eb4e898f' User entered '01 May 2021 16:24:38'	System	01 May 2021 20:24:55
	System	01 May 2021 20:24:55

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:00:50

US3022208

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:49:49

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:00:50
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:00:50

US3022208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:49:49

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 09:19:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-03-02T09:54:49-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '925ed77b-5970-41b4-b896-de04d0a846f2'	(b) (4), (b) (6)	02 Mar 2021 14:55:03
User entered 'No (N)'	System	02 Mar 2021 14:55:03

US3022208

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:49:49

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:19:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (055dec66dc3e364a)', Time: '2021-03-02T09:54:58-05:00', User OID: 'PatientReportedOutcome (US3022208)', ODM File OID: '925ed77b-5970-41b4-b896-de04d0a846f2'	(b) (4), (b) (6)	
User entered '02 Mar 2021 09:54:58'	System	02 Mar 2021 14:55:03

US3022208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:50:26

US3022208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:17
User signature succeeded.	Paul Bradley (b) (4)	29 Apr 2021 19:02:10
User closed query 'Per CDM (RQ): Please note Safety Day 85 should be after Day 57.Safety Call Day 85 happens on 85th day after visit 1, it cannot be before day 57. Day 85 should happen after Day 57. Kindly update appropriately.' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 06:53:53
Query 'Per CDM (RQ): Please note Safety Day 85 should be after Day 57.Safety Call Day 85 happens on 85th day after visit 1, it cannot be before day 57. Day 85 should happen after Day 57. Kindly update appropriately.' answered with 'these dates are correct ' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 15:35:40
User opened query 'Per CDM (RQ): Please note Safety Day 85 should be after Day 57.Safety Call Day 85 happens on 85th day after visit 1, it cannot be before day 57. Day 85 should happen after Day 57. Kindly update appropriately.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:50:35
User closed query 'Per CDM re-query: Response noted; however safety call 85 (1) is prior to visit 3 day 57. Kindly review, reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:50:35
Query 'Per CDM re-query: Response noted; however safety call 85 (1) is prior to visit 3 day 57. Kindly review, reconcile and update accordingly. Otherwise clarify. Thank you.' answered with 'this is correct ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:02:05
User opened query 'Per CDM re-query: Response noted; however safety call 85 (1) is prior to visit 3 day 57. Kindly review, reconcile and update accordingly. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 14:37:17
User closed query 'Per CDM: Visits Safety Call Day 85 and Safety Call Day 119 are both dated 14DEC2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 14:34:53

US3022208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Visits Safety Call Day 85 and Safety Call Day 119 are both dated 14DEC2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' answered with 'updated ' (Site from DM). Signature has been broken.	(b) (4), (b) (6)	31 Mar 2021 17:19:36
	(b) (4), (b) (6)	31 Mar 2021 17:19:22
User entered '10 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	31 Mar 2021 17:19:22
User opened query 'Per CDM: Visits Safety Call Day 85 and Safety Call Day 119 are both dated 14DEC2020, however it is not possible for these two visits to be on the same day per the schedule of events. Please confirm the date for each visit or amend one of them to 'No' if it was not completed. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	25 Mar 2021 21:29:36
	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:50:26

US3022208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	15 Dec 2020 19:50:26

US3022208

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:01:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:50:26

US3022208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Dec 2020 19:50:29

US3022208

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:23:39
User entered 'I'	(b) (4), (b) (6) System	15 Dec 2020 19:50:29

US3022208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:54:08

US3022208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14 Dec 2020'	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:54:08

US3022208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 15:54:08

US3022208

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 15:54:08

US3022208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 15:54:11

US3022208

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User entered 'I'	System	06 Jan 2021 15:54:11

US3022208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:14:31

US3022208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '14 Jan 2021'	(b) (4), (b) (6)	02 Mar 2021 20:14:31

US3022208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Mar 2021 20:14:31

US3022208

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 20:14:31

US3022208

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:14:35

US3022208

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User entered 'I'	System	02 Mar 2021 20:14:35

US3022208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:14:48

US3022208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '11 Feb 2021'	(b) (4), (b) (6)	02 Mar 2021 20:14:48

US3022208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Mar 2021 20:14:48

US3022208

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4), (b) (6)	02 Mar 2021 20:14:48

US3022208

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:14:54

US3022208

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:49:46
User entered 'I'	System	02 Mar 2021 20:14:54

US3022208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:15:09

US3022208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '02 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 20:15:09

US3022208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Mar 2021 20:15:09

US3022208

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered 'VISIT4'	(b) (4), (b) (6) System	02 Mar 2021 20:15:09

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered empty.	(b) (4), (b) (6) System	30 Mar 2021 16:45:58

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 10:17:13

US3022208

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 10:17:13

US3022208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:15:16

US3022208

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '02 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 20:15:16

US3022208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:15:25

US3022208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '02 Mar 2021'	(b) (4), (b) (6)	02 Mar 2021 20:15:25

US3022208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered '10:17'	(b) (4), (b) (6)	02 Mar 2021 20:15:25

US3022208

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered '02 Mar 2021 10:17'	(b) (4), (b) (6) System	02 Mar 2021 20:15:25

US3022208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Mar 2021 20:15:32

US3022208

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:17:13
User entered 'I'	(b) (4), (b) (6) System	02 Mar 2021 20:15:32

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:49:49

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	(b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:49:49

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '19 Oct 2020'	(b) (4) (b) (4), (b) (6)	03 Dec 2020 18:33:53

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '19 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Clinic (Clinic)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD28'	System	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '19 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14:50'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Oct 2020 14:50'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Height (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '174' cm	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:37:22
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '98.4' kg	(b) (4) Shanice Bennett (b) (4)	20 Nov 2020 16:37:22
DataPoint set to visible.	(b) (4) System	20 Nov 2020 16:36:35

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '36.9' C	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (Oral)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '68'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '18'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '120'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '86'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	20 Nov 2020 16:37:22

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:34

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '19 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:34

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:49:49

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:40

US3022208

Folder: Convalescence Visit Day 28 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 14:49:49

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Nov 2020 05:48:52
User opened query 'Per GCL Lab Reconciliation: SARS-CoV-2 serum sample: Sample dated 19 OCT 2020 is reported under Convalescence Visit Day 28 in EDC, however the same is reported in the Illness Visit Day 1 in PPD Central lab. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 05:35:02
User entered '19 Oct 2020'	Shanice Bennett (b) (4) (b) (4)	20 Nov 2020 16:37:40

US3022208

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:30:51

US3022208

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:30:51

US3022208

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[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 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:30:51

US3022208

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

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 13:30:51

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[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 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Apr 2021 14:48:00
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:19:57

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4)	05 Apr 2021 14:48:00
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	06 Mar 2021 13:19:57
	System	

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 14:48:00
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:48:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 14:48:00
User entered 'mRNA-1273 (mRNA-1273)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:48:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:41
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	05 Apr 2021 14:48:00
User entered 'Not Administered (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Apr 2021 14:48:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered empty.	System	05 Apr 2021 14:48:00
User entered 'I'	System	25 Jan 2021 13:31:22

US3022208

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

Form: Unblinding

Generated On: 09 Jun 2021 14:49:49

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'I'	System	25 Jan 2021 13:31:22

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered empty.	System	25 Jan 2021 13:33:07
DataPoint set to visible.	System	25 Jan 2021 13:31:22

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered empty.	System	25 Jan 2021 13:33:07
DataPoint set to visible.	System	25 Jan 2021 13:31:22

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '10:35'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered '22 Jan 2021 10:35'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '70'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'bpm'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'breaths/min'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '128'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'mmHg'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '80'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'mmHg'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:49:49

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered empty.	System	25 Jan 2021 13:33:07
DataPoint set to visible.	System	25 Jan 2021 13:31:22

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '11:41'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered '22 Jan 2021 11:41'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '36.7' C	(b) (4), (b) (6)	25 Jan 2021 13:33:07

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '84'	(b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'bpm'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '16'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'breaths/min'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '130'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'mmHg'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '88'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:07

US3022208

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'mmHg'	System	25 Jan 2021 13:33:07

US3022208

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:32:04

US3022208

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:32:04

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'mRNA-1273'	System	25 Jan 2021 13:33:25
DataPoint set to visible.	System	25 Jan 2021 13:31:22

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '11:11'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered '22 Jan 2021 11:11'	System	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'ONCE'	System	25 Jan 2021 13:33:25

US3022208

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

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 13:33:25

US3022208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:32

US3022208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:32

US3022208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '09:15'	(b) (4), (b) (6)	25 Jan 2021 13:31:32

US3022208

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered '22 Jan 2021 09:15'	System	25 Jan 2021 13:31:32

US3022208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:40

US3022208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:40

US3022208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:49

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '09:38'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:40

US3022208

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:49:49

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered '22 Jan 2021 09:38'	System	25 Jan 2021 13:31:40

US3022208

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

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 13:31:56

US3022208

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

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:56:05
User entered 'I'	System	25 Jan 2021 13:31:56

US3022208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:21:20

US3022208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '29 Jan 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:21:20

US3022208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:21:20

US3022208

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:21:20

US3022208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 15:21:25

US3022208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User entered 'I'	System	02 Feb 2021 15:21:25

US3022208

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:15:03
User entered '1'	System	02 Feb 2021 15:21:25
DataPoint set to visible.	System	02 Feb 2021 15:21:25

US3022208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User closed query 'Per CDM: Per sponsor review, please complete Vital Signs page for this visit. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:36:32
Query 'Per CDM: Per sponsor review, please complete Vital Signs page for this visit. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:22:19
User opened query 'Per CDM: Per sponsor review, please complete Vital Signs page for this visit. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:19:18
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
Signature has been broken.	(b) (4), (b) (6)	23 Feb 2021 18:57:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:57:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	03 Feb 2021 06:31:26
Query 'Data is required. Please complete.' answered with 'entered in error' (Site from System).	(b) (4), (b) (6)	02 Feb 2021 15:26:55
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Feb 2021 15:26:44
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 15:26:44
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Feb 2021 15:26:17

US3022208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User closed query 'Per GCL Lab Reconciliation: Immunogenicity sample dated 23Feb2021 for Visit OL-D29 is found in PPD Central Lab: however, Immunogenicity Assessment form is missing. Please review and confirm if the sample was collected and update accordingly. Thanks.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:36:36
Query 'Per GCL Lab Reconciliation: Immunogenicity sample dated 23Feb2021 for Visit OL-D29 is found in PPD Central Lab: however, Immunogenicity Assessment form is missing. Please review and confirm if the sample was collected and update accordingly. Thanks.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 14:48:43
User opened query 'Per GCL Lab Reconciliation: Immunogenicity sample dated 23Feb2021 for Visit OL-D29 is found in PPD Central Lab: however, Immunogenicity Assessment form is missing. Please review and confirm if the sample was collected and update accordingly. Thanks.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 02:32:25
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
Signature has been broken.	(b) (4), (b) (6)	23 Feb 2021 18:57:03
User entered '23 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:57:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 15:26:44
User entered '01 Feb 2021'	(b) (4), (b) (6)	02 Feb 2021 15:26:17

US3022208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
Signature has been broken.	(b) (4), (b) (6)	23 Feb 2021 18:57:03
User entered 'Clinic (Clinic)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:57:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 15:26:44
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	02 Feb 2021 15:26:17

US3022208

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:49:49

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'OLD29'	System	23 Feb 2021 18:57:03
User entered empty.	System	02 Feb 2021 15:26:44
User entered 'OLD29'	System	02 Feb 2021 15:26:17

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '23 Feb 2021'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '10:13'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered '23 Feb 2021 10:13'	System	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '36.6' C	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered 'Oral (Oral)'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '79'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'bpm'	System	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '14'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'breaths/min'	System	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '131'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'mmHg'	System	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '88'	(b) (4), (b) (6)	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'mmHg'	System	05 Apr 2021 15:22:10

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20

US3022208

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:49:49

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '10:13'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered '23 Feb 2021 10:13'	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '36.6' C	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'Oral (Oral)'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '79'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'bpm'	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '14'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'breaths/min'	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '131'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'mmHg'	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '88'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:49:49

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'mmHg'	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'No (N)'	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:49:49

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:59:38

US3022208

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 18:57:12

US3022208

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:49:49

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:57:12

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:58:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User closed query 'Was study treatment given? is No, System however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	(b) (4)	23 Feb 2021 18:59:09
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:59:09
User opened query 'Was study treatment given? is No, however If No, reason not given is not provided. Please review and reconcile.' (Site from System).	System	23 Feb 2021 18:58:46
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

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)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'subject received moderna on first dose and will not receive anymore' reason for change:	(b) (4), (b) (6)	23 Feb 2021 18:59:09
Data Entry Error		
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
DataPoint set to visible.	System	05 Apr 2021 14:48:00
User entered empty.	System	23 Feb 2021 18:58:46
User entered 'MRNA-1273 OR PLACEBO'	System	23 Feb 2021 18:57:33
DataPoint set to invisible.	System	02 Feb 2021 15:21:25

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:58:46
User entered '23 Feb 2021'	(b) (4), (b) (6)	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:58:46
User entered '10:36'	(b) (4), (b) (6)	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:58:46
User entered '23 Feb 2021 10:36'	System	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	23 Feb 2021 18:58:46
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:58:46
User entered 'ONCE'	System	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:49:49

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered empty.	System	23 Feb 2021 18:58:46
User entered 'INTRAMUSCULAR'	System	23 Feb 2021 18:57:33

US3022208

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 14:48:35

US3022208

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '23 Feb 2021'	(b) (4), (b) (6)	05 Apr 2021 14:48:35

US3022208

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
User entered '10:36'	(b) (4), (b) (6)	05 Apr 2021 14:48:35

US3022208

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:49:49

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered '23 Feb 2021 10:36'	System	05 Apr 2021 14:48:35

US3022208

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 18:57:16

US3022208

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 04:11:20
User entered 'I'	System	23 Feb 2021 18:57:16

US3022208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:38:20
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:39:02

US3022208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:38:20
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:39:02

US3022208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:38:20
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:39:02

US3022208

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:49:49

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:38:20
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:39:02

US3022208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:38:20
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:39:08

US3022208

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:49:49

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 03:38:20
User entered 'I'	System	01 Mar 2021 14:39:08

US3022208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:49:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:39
User closed query 'Per CDM: Per sponsor review, please confirm if subject tested positive for COVID-19. If confirmed, please enter AE as required per CCGs. (Pgs 29 and 32).' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 08:59:17
Query 'Per CDM: Per sponsor review, please confirm if subject tested positive for COVID-19. If confirmed, please enter AE as required per CCGs. (Pgs 29 and 32).' answered with 'Covid ae as made inactive due to subject actually having congestive heart failure ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:26:27
User opened query 'Per CDM: Per sponsor review, please confirm if subject tested positive for COVID-19. If confirmed, please enter AE as required per CCGs. (Pgs 29 and 32).' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 15:21:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM: Please note that there are two AEs where Action taken with investigational product = Investigational Product Withdrawn (AE#1 and AE#3) Please review and ensure only the AE which is the primary reason for dosing discontinuation has Action taken = IP withdrawn. Update as appropriate and reconcile with the Dosing discontinuation page. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 06:31:05
Query 'Per CDM: Please note that there are two AEs where Action taken with investigational product = Investigational Product Withdrawn (AE#1 and AE#3) Please review and ensure only the AE which is the primary reason for dosing discontinuation has Action taken = IP withdrawn. Update as appropriate and reconcile with the Dosing discontinuation page. ' answered with 'These aes happened at the same time- due to both of them ip was withdrawn ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:24:20

US3022208

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:49:49

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Please note that there are two AEs where Action taken with investigational product = Investigational Product Withdrawn (AE#1 and AE#3) Please review and ensure only the AE which is the primary reason for dosing discontinuation has Action taken = IP withdrawn. Update as appropriate and reconcile with the Dosing discontinuation page. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Feb 2021 11:55:36
	(b) (4), (b) (6)	10 Nov 2020 18:36:33
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:39:35
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:18:27
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:31:56
User entered	System	15 Sep 2020 14:31:39
'USA-US051-2020-mRNA-1273-P301000003'		
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 14:31:39

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:18:29
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Heart failures NEC, PT: Cardiac failure congestive, LLT: Congestive heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:47:55
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Sep 2020 16:47:55
	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 16:46:45
User entered 'CONGESTIVE HEART FAILURE'	Shanice Bennett (b) (4)	14 Sep 2020 16:46:11
reason for change: Data Entry Error	(b) (4)	
Data point term sent to Coder	System	14 Sep 2020 16:41:30
User entered 'CONGESTION HEART FAILURE'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:31
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:33
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:35
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:29:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Un-verified.	Shanice Bennett (b) (4)	07 Dec 2020 19:55:19
User entered '07 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	07 Dec 2020 19:55:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:18:20
User closed query 'PV Query: Please confirm the start date as symptoms started on 08 SEP but start date is listed as 10 SEP. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:01:08
Query 'PV Query: Please confirm the start date as symptoms started on 08 SEP but start date is listed as 10 SEP. ' answered with 'date is correct ' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:32:31
User opened query 'PV Query: Please confirm the start date as symptoms started on 08 SEP but start date is listed as 10 SEP. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 17:16:27
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:22
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:12
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Sep 2020 16:42:05
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:42:05
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	14 Sep 2020 16:41:27
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:14
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:41:27
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 16:41:27
User entered '14 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:41:27
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:16
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:08
User closed query 'PV Query: The event intensity is "Grade 4" for this event of Congestive heart failure. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.	(b) (4), (b) (6)	05 Oct 2020 13:01:19
' (Site from Safety). Query 'PV Query: The event intensity is "Grade 4" for this event of Congestive heart failure. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.	Shanice Bennett (b) (4) (b) (4)	02 Oct 2020 21:32:48
' answered with 'yes per PI due to the patient being hospitalized ' (Site from Safety). User opened query 'PV Query: The event intensity is "Grade 4" for this event of Congestive heart failure. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.	(b) (4), (b) (6)	21 Sep 2020 17:52:34
' (Site from Safety). User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:07
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Sep 2020 16:42:35
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	14 Sep 2020 16:40:40
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:00
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:02
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:17:56
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:17:49
User entered '10 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:17:51
User entered '14 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:17:53
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:42:35
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:51
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:47
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:46
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:18:44
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:16:23
User closed query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:41:27
User opened query 'Action taken with investigational product is recorded as Withdrawn; however Relationship is not recorded as Related. Please review and reconcile.' (Site from System).	System	14 Sep 2020 16:40:40
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 19:16:22
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigation Product Withdrawn. However, Dosing Discontinuation details does not reflect this AE as a reason for discontinuation. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Nov 2020 21:58:56
Query 'Per DM CLR: Action Taken with Investigational Product = Investigation Product Withdrawn. However, Dosing Discontinuation details does not reflect this AE as a reason for discontinuation. Please review and update applicable details as appropriate. Otherwise, clarify.' answered with 'this is correct' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 23:45:01
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigation Product Withdrawn. However, Dosing Discontinuation details does not reflect this AE as a reason for discontinuation. Please review and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:19:21
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	12 Nov 2020 10:20:06
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:38:48
User closed query 'Per source action taken with IP is IP withdrawn. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:38:46
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'updated' (Site from System).	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:09:37
Query 'Per source action taken with IP is IP withdrawn. Please confirm with source and update accordingly.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:09:31

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

Action taken with investigational product

Audit	User	Time (GMT)
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	10 Nov 2020 20:08:54
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:08:54
User opened query 'Per source action taken with IP is IP withdrawn. Please confirm with source and update accordingly.' (Site from CRA).	(b) (4), (b) (6) (b) (4)	10 Nov 2020 19:04:26
User entered 'Dose Delayed (DOSE DELAYED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:41:27
User entered 'Investigational Product Withdrawn (WITHDRAWN)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:07
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	(b) (4)	
DataPoint Un-verified.	System	02 Feb 2021 15:22:44
	(b) (4), (b) (6)	02 Feb 2021 15:22:44
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 15:22:44
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Feb 2021 15:22:31
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 08:17:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:15:16
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:08:54
	(b) (4)	
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'pending medical records' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 21:32:58
	(b) (4)	
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded for this condition which is unexpected. Please review and ensure that CM/ConProc for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:43:04

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

None

Audit	User	Time (GMT)
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:03
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM, per DM CLR re-query: Response " There are no medications documented in the chart under conmed log for this condition." is noted. If no medication is taken, then please remove the tick from this field. Update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 11:44:57
Query 'Per CDM, per DM CLR re-query: Response " There are no medications documented in the chart under conmed log for this condition." is noted. If no medication is taken, then please remove the tick from this field. Update as appropriate or clarify. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	03 Dec 2020 18:35:02
DataPoint Un-verified.	(b) (4), (b) (6)	03 Dec 2020 18:34:55
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	03 Dec 2020 18:34:55
User closed query 'Per CDM (CLR Re-Query): response of 'will update' is noted; however the update has not been made. Please reconcil and update Concomitant Medications Form.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:42:47
User opened query 'Per CDM, per DM CLR re-query: Response " There are no medications documented in the chart under conmed log for this condition." is noted. If no medication is taken, then please remove the tick from this field. Update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:42:46
Query 'Per CDM (CLR Re-Query): response of 'will update' is noted; however the update has not been made. Please reconcil and update Concomitant Medications Form.' answered with 'There are no medications documented in the chart under conmed log for this condition.' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:48:16
User opened query 'Per CDM (CLR Re-Query): response of 'will update' is noted; however the update has not been made. Please reconcil and update Concomitant Medications Form.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:07:46

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:07:46
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'will update' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 23:45:19
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	19 Nov 2020 19:20:17
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:39:02
User closed query 'Per source medication was given. Please reconcile with medical records and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:39:01
Query 'Per source medication was given. Please reconcile with medical records and update accordingly.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:09:42
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:08:54
User opened query 'Per source medication was given. Please reconcile with medical records and update accordingly.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:05:17
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:31:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per DM CLR-RQ: Response noted. However, please note that echocardiogram and ECG are diagnostic procedures. This field will only be checked if therapeutic surgery are administered. Either update Con Proc eCRF to include a diagnostic procedure or untick this field. ' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 05:54:04
Query 'Per DM CLR-RQ: Response noted. However, please note that echocardiogram and ECG are diagnostic procedures. This field will only be checked if therapeutic surgery are administered. Either update Con Proc eCRF to include a diagnostic procedure or untick this field. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 15:23:04
DataPoint Un-verified.	(b) (4), (b) (6)	02 Feb 2021 15:22:31
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	02 Feb 2021 15:22:31
User opened query 'Per DM CLR-RQ: Response noted. However, please note that echocardiogram and ECG are diagnostic procedures. This field will only be checked if therapeutic surgery are administered. Either update Con Proc eCRF to include a diagnostic procedure or untick this field. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 03:12:59
User closed query 'Per DM CLR: RQ: Response noted, however, there is still no update in the Con Proc eCRF for a therapeutic procedure for this AE. Update as appropriate. Please don't close this query if there is no update in Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 03:12:59

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: RQ: Response noted, however, there is still no update in the Con Proc eCRF for a therapeutic procedure for this AE. Update as appropriate. Please don't close this query if there is no update in Con Proc eCRF.' answered with 'there is an echocardiogram AND ecg noted in con prc' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:08:36
User opened query 'Per DM CLR: RQ: Response noted, however, there is still no update in the Con Proc eCRF for a therapeutic procedure for this AE. Update as appropriate. Please don't close this query if there is no update in Con Proc eCRF.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:09:54
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures are a Diagnostic procedures rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 14:27:40
Query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures are a Diagnostic procedures rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' answered with 'will update' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 23:45:14
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, the corresponding procedures are a Diagnostic procedures rather than therapeutic. Please review and update to record the therapeutic procedure for this AE as appropriate OR update Other Action Taken. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 19:19:56
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:16:23
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:16:21
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:15:24

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per source procedures were completed. Please confirm and update. Also please add to concomitant procedures page.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:39:09
Query 'Per source procedures were completed. Please confirm and update. Also please add to concomitant procedures page.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:09:48
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 20:08:54
User opened query 'Per source procedures were completed. Please confirm and update. Also please add to concomitant procedures page.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:15:31
Query 'Per source procedures were completed. Please confirm and update.' canceled (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:15:03
User opened query 'Per source procedures were completed. Please confirm and update.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 19:14:15
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:30:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	07 Dec 2020 19:59:23
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	07 Dec 2020 19:58:05
DataPoint Un-verified.	Shanice Bennett (b) (4)	07 Dec 2020 19:58:05
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Shanice Bennett (b) (4)	07 Dec 2020 19:58:05
Data Entry Error	(b) (4)	
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 13:43:18
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' answered with 'SEQUELAE SPECIFIED DOWN BELOW' (Site from Safety).	(b) (4), (b) (6)	03 Dec 2020 18:35:19
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:46:15
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:20
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' answered with 'sequel is updated' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 15:53:14
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:04:44

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 14:50:47
User closed query 'Please confirm with source or clarify. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 17:09:43
Query 'Please confirm with source or clarify. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:27:26
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	13 Nov 2020 23:27:21
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:27:21
User opened query 'Please confirm with source or clarify. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:21:24
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae' . Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:15:04
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae' . Please specify sequelae.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	10 Nov 2020 20:10:34
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	10 Nov 2020 20:10:28
DataPoint Un-verified.	Shanice Bennett (b) (4)	10 Nov 2020 20:10:28
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:10:28
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:53
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae' . Please specify sequelae.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:23:45
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:30:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Un-verified.	Shanice Bennett (b) (4)	07 Dec 2020 19:59:23
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	07 Dec 2020 19:59:23
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:15:51
User entered 'DUE TO CONGESTIVE HEART FAILURE IS A NEW DIAGNOSIS.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:46:11
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:41:27
User entered 'Subject reported that she was hospitalized and being discharged today. On 08Sep2020 she began to have shortness of breath with excretion. On 10Sep2020 she was seen by her PCP and told she had fluid on her lungs and was sent to the ER for an evaluation. She reports she was diagnosed with congestive heart failure and tested positive for COVID-19. She is being prescribed new medications (Losartan and Abilify) but unsure of doses. Pending medical records.' (non-conformant).	Shanice Bennett (b) (4)	14 Sep 2020 16:41:27
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:40
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:40:40

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Narrative = MEDICATION. However, there is no medication recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 12:59:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Query 'Per DM CLR: Narrative = MEDICATION. However, there is no medication recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:28:29
User opened query 'Per DM CLR: Narrative = MEDICATION. However, there is no medication recorded in the ConMed eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:31:49
User closed query 'PV Query: Please consider adding Cocaine abuse as an SAE.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:45:14
User closed query 'PV Query: Per the medical record, the patient had worsening shortness of breath for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had palpitations for 1 week before coming to ER. Because onset date should be when the subject began to experience symptoms, not when the event became serious, please confirm whether reconsideration of onset date is necessary. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:45:11
User closed query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 14:45:07
Query 'PV Query: Please consider adding Cocaine abuse as an SAE.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	07 Dec 2020 19:55:30

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Per the medical record, the patient had worsening shortness of breath for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had palpitations for 1 week before coming to ER. Because onset date should be when the subject began to experience symptoms, not when the event became serious, please confirm whether reconsideration of onset date is necessary. If not, please explain.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	07 Dec 2020 19:55:04
Query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' answered with 'Per PI no, Cardiomyopathy as a symptom of congestion heart failure ' (Site from Safety).	Shanice Bennett (b) (4)	07 Dec 2020 19:54:42
User opened query 'PV Query: Please consider adding Cocaine abuse as an SAE.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:46:40
User opened query 'PV Query: Per the medical record, the patient had worsening shortness of breath for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had palpitations for 1 week before coming to ER. Because onset date should be when the subject began to experience symptoms, not when the event became serious, please confirm whether reconsideration of onset date is necessary. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:46:34
User opened query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 00:46:23
User closed query 'Per CDM, per DM CLR re-query: Please review and verify if any medications have been taken and update the Con Med page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 08:39:46
Query 'Per CDM, per DM CLR re-query: Please review and verify if any medications have been taken and update the Con Med page as appropriate. ' answered with 'There were no medications taken or updated on the conmed log' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:47:45

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EAB) (1725)

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Audit	User	Time (GMT)
User closed query 'PV Query: Per the medical record, the patient had worsening SOB for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had dry cough and palpitations for 1 week before coming to ER. Please confirm reconsideration of onset date is necessary. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:56
User closed query 'PV Query: Did suicidal ideation prior to the event of congestive heart failure occurred after IP administration? If so, please confirm that suicidal ideation meets definition of AE or SAE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:52
User closed query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:47
User closed query 'PV Query: The subject was reported as positive for COVID-19. Please consider adding it to the EDC' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 14:05:31
User opened query 'Per CDM, per DM CLR re-query: Please review and verify if any medications have been taken and update the Con Med page as appropriate. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:34:04
User closed query 'Per DM CLR: SAE NARRATIVE: SHE IS BEING PRESCRIBED NEW MEDICATIONS (LOSARTAN AND ABILIFY). Please review and confirm if the following medications has been taken by the subject. If yes, please ensure that this information is captured in the appropriate eCRF. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 11:34:04
Query 'PV Query: Per the medical record, the patient had worsening SOB for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had dry cough and palpitations for 1 week before coming to ER. Please confirm reconsideration of onset date is necessary. If not, please explain.' answered with 'subject stated that she denied cough but palpitation yes. ' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:08:54

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Did suicidal ideation prior to the event of congestive heart failure occurred after IP administration? If so, please confirm that suicidal ideation meets definition of AE or SAE. If not, please explain.' answered with 'no' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:08:03
Query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' answered with 'confirmed' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:07:46
Query 'PV Query: The subject was reported as positive for COVID-19. Please consider adding it to the EDC' answered with 'I did that and they asked me to remove it due to no symptoms ' (Site from Safety).	Shanice Bennett (b) (4)	20 Nov 2020 16:07:33
User opened query 'PV Query: Per the medical record, the patient had worsening SOB for 3 days before coming to ER on 10-SEP-2020. Per the medical record, the patient had dry cough and palpitations for 1 week before coming to ER. Please confirm reconsideration of onset date is necessary. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:05:45
User opened query 'PV Query: Did suicidal ideation prior to the event of congestive heart failure occurred after IP administration? If so, please confirm that suicidal ideation meets definition of AE or SAE. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:05:24
User opened query 'PV Query: Please confirm that cardiomyopathy meets definition of SAE as a diagnosis of congestive heart failure. If so, please reconsider the event term. If not, please explain.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:05:12
User opened query 'PV Query: The subject was reported as positive for COVID-19. Please consider adding it to the EDC' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 15:04:57
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:18:45
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:15:19

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EAB) (1725)

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Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 20:15:15
User entered 'UPDATED SAE WITH MEDIAL RECORDS HAVE BEEN EMAILED OVER. MEDICATION AND PROCEDURE. SAE due to Cocaine abuse.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	11 Nov 2020 15:28:31
User closed query 'Please update Narrative with information from medical history. Please also add all medications taken.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:40:21
Query 'Please update Narrative with information from medical history. Please also add all medications taken.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	10 Nov 2020 20:15:04
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	10 Nov 2020 20:14:51
Query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	10 Nov 2020 20:14:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:14:39
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	10 Nov 2020 20:14:39
User entered 'updated SAE with medial records have been emailed over. medication and procedure.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:14:39
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	10 Nov 2020 20:08:54
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:08:54

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Please update Narrative with information from medical history. Please also add all medications taken.' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 18:38:43
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:24:00
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	09 Oct 2020 17:23:18
User closed query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:01:28
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 13:01:26
Query 'Per DM CLR: SAE NARRATIVE: SHE IS BEING PRESCRIBED NEW MEDICATIONS (LOSARTAN AND ABILIFY). Please review and confirm if the following medications has been taken by the subject. If yes, please ensure that this information is captured in the appropriate eCRF. Otherwise, provide clarification.' answered with 'pending medical records' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 21:33:23
Query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae ' answered with 'pending medical records' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:33:13
Query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable. ' answered with 'pending medical records' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:33:06

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Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE NARRATIVE: SHE IS BEING PRESCRIBED NEW MEDICATIONS (LOSARTAN AND ABILIFY). Please review and confirm if the following medications has been taken by the subject. If yes, please ensure that this information is captured in the appropriate eCRF. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 20:42:36
User opened query 'PV Query: Outcome of the event of Congestive heart failure was reported as 'recovered with sequelae'. Please specify sequelae ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 17:17:21
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test (BNP, echocardiogram, chest x-ray, etc) results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 17:16:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:41:41
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 16:41:41
User entered 'Subject reported that she was hospitalized and being discharged today. On 08Sep2020 she began to have shortness of breath with excretion. On 10Sep2020 she was seen by her PCP and told she had fluid on her lungs and was sent to the ER for an evaluation. She reports she was diagnosed with congestive heart failure and tested positive for COVID-19. She is being prescribed new medications (Losartan and Abilify) but unsure of doses. Pending medical records.' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:41:41
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:40:40
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	14 Sep 2020 16:40:40

US3022208

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:49:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 16:42:35

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 14:48:37
User entered 'USA-US051-2020-mRNA-1273-P301000003'	(b) (4), (b) (6)	08 Dec 2020 14:47:59

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User coded data point as SOC: Psychiatric disorders, HLT: Psychiatric disorders NEC, HLT: Substance related and addictive disorders, PT: Drug abuse, LLT: Cocaine abuse - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 19:58:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Dec 2020 19:58:55
Data point term sent to Coder	System	07 Dec 2020 19:57:23
User entered 'Cocaine Abuse'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:22
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:30
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 21:13:25
Query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 21:08:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 21:08:54
User opened query 'Per DM CLR: Please review AE term reported as this is not included as one of the solicited AE per protocol. Review if this should be recorded as Unsolicited event and update this field to NO. Review and update as appropriate. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:08:18
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:34
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:36
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'PV Query: The event congestive heart failure with an onset date of 07 Sep 2020 has been reported as due to cocaine abuse, which started on 10 Sep 2020. Please clarify the onset date of cocaine abuse.' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 18:25:55
Query 'PV Query: The event congestive heart failure with an onset date of 07 Sep 2020 has been reported as due to cocaine abuse, which started on 10 Sep 2020. Please clarify the onset date of cocaine abuse.' answered with 'per source this date is correct' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 21:13:49
User opened query 'PV Query: The event congestive heart failure with an onset date of 07 Sep 2020 has been reported as due to cocaine abuse, which started on 10 Sep 2020. Please clarify the onset date of cocaine abuse.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 19:03:23
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:39
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:37:58
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'I'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '14 Sep 2020'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:15
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:20
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:22
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:24
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:29
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:31
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:55:51
Query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' answered with 'yes dosing discontinuation has already been completed in edc' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 13:52:18
User opened query 'Per DM CLR: Action Taken with Investigational Product = Investigational Product Withdrawn. Ensure this is reflected in dosing discontinuation if applicable. Review and update. Else, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 05:54:33
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	07 Dec 2020 19:58:26
User entered 'Dose Delayed (DOSE DELAYED)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:37
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 11:33:53
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'conmed procedure is added for congestive heart failure' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 13:53:30
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	23 Jan 2021 05:54:41
User entered 'I'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:42
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 19:38:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	07 Dec 2020 19:57:39
User entered 'SAE congestive heart failure' reason for change: Data Entry Error	Shanice Bennett (b) (4)	07 Dec 2020 19:57:39
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4)	
User entered empty.	System	07 Dec 2020 19:57:09
	Shanice Bennett (b) (4)	07 Dec 2020 19:57:09
	(b) (4)	

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 19:57:09

US3022208

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:49:49

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 19:57:09

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:49:49

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:39
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User closed query 'Per CDM, DM CLR re-query: Please clarify your response. Please also note that there is no Con Med recorded for Diary Dose 1, Day 2 (21 Aug); with an indication Underarm Gland Swelling or Tenderness. Review and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 16:33:37
Query 'Per CDM, DM CLR re-query: Please clarify your response. Please also note that there is no Con Med recorded for Diary Dose 1, Day 2 (21 Aug); with an indication Underarm Gland Swelling or Tenderness. Review and update as appropriate, else clarify. ' answered with 'Tylenol was taken for for pain' (Site from DM).	(b) (4), (b) (6)	19 Feb 2021 16:29:31
User opened query 'Per CDM, DM CLR re-query: Please clarify your response. Please also note that there is no Con Med recorded for Diary Dose 1, Day 2 (21 Aug); with an indication Underarm Gland Swelling or Tenderness. Review and update as appropriate, else clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:47:06
User closed query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 13:47:06
Query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'subject did that due to ae and sae' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 19:39:30

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Per Diary Dose 1 Day 2, Underarm Gland Swelling or Tenderness = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 05:13:53
Query 'Please add all conmeds per source. Thank you' canceled (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:21:53
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:21:48
User opened query 'Please add all conmeds per source. Thank you' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 17:42:06
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:14
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 16:30:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 16:30:50
Data point term sent to Coder	System	19 Feb 2021 16:29:53
Coding entries removed.	(b) (4), (b) (6)	19 Feb 2021 16:29:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 00:47:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Aug 2020 00:47:43
Data point term sent to Coder	System	27 Aug 2020 21:27:54
User entered 'TYLENOL'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 21:27:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Aug 2020 21:27:27
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:27:27
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Aug 2020 21:26:54
User entered empty.	Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE/ UNDERARM SWELLING is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE/ UNDERARM SWELLING did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:29:57
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE/ UNDERARM SWELLING is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE/ UNDERARM SWELLING did not meet the AE reporting criteria.' answered with 'No AE needed' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:27:09

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE/ UNDERARM SWELLING is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE/ UNDERARM SWELLING did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 00:25:42
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	19 Feb 2021 16:29:48
User entered 'PAIN AT THE INJECTION SITE/ UNDERARM SWELLING' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 16:29:48
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User closed query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of PAIN AT INJECTION SITE does not meet any of the remaining AE reporting criteria, else add an entry and appropriate details to the AE eCRF. Thank you.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 07:21:17
Query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of PAIN AT INJECTION SITE does not meet any of the remaining AE reporting criteria, else add an entry and appropriate details to the AE eCRF. Thank you.' answered with 'Because this is pertaining to diary after vaccination' (Site from DM).	Shanice Bennett (b) (4)	22 Oct 2020 15:42:17
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per CDM, per DM CLR re-query: Response is noted; however, please confirm in a query response that the AR of PAIN AT INJECTION SITE does not meet any of the remaining AE reporting criteria, else add an entry and appropriate details to the AE eCRF. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:45:02
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	19 Oct 2020 12:45:02
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' answered with 'no MAAE or SAE ' (Site from DM).	Shanice Bennett (b) (4)	02 Oct 2020 17:36:45

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the PAIN AT THE INJECTION SITE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of PAIN AT THE INJECTION SITE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	12 Sep 2020 03:10:46
User entered 'PAIN AT THE INJECTION SITE'	Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '500'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'mg (mg)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'twice daily (BID)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '21 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '21 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	27 Aug 2020 21:26:54
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User entered '2'	(b) (4), (b) (6) System	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User entered '1'	(b) (4), (b) (6) System	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:32
User entered '804 (804)'	(b) (4), (b) (6) System	27 Aug 2020 21:26:54

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:56:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 19:56:39
Data point term sent to Coder	System	10 Nov 2020 19:55:47
User entered 'hydrocodone/Acetaminophen'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Chronic Pain'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '7.5/325'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'as needed (PRN)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Nov 2020 19:55:06

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL, PRODUCTSYNONYM: POLYETHYLENE GLYCOL [MACROGOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 06:52:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Nov 2020 06:52:49
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:33:43
Data point term sent to Coder	System	10 Nov 2020 19:56:48
User entered 'polyethylene glycol'	Shanice Bennett (b) (4)	10 Nov 2020 19:55:49
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Chronic Constipation'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '17'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'g (g)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'once daily (QD)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:55:49

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User coded data point as ATC: ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS, ATC: ENDOCRINE THERAPY, ATC: HORMONE ANTAGONISTS AND RELATED AGENTS, ATC: AROMATASE INHIBITORS, PRODUCT: ANASTROZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:57:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Nov 2020 19:57:40
Data point term sent to Coder	System	10 Nov 2020 19:56:49
User entered 'Anastrozole'	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	10 Nov 2020 20:18:04
User entered 'No (N)'	(b) (4)	
	Shanice Bennett (b) (4)	10 Nov 2020 19:56:42
	(b) (4)	

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Breast Cancer'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'mg (mg)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'once daily (QD)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'un UNK 2014'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered '0'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:33:43
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Nov 2020 19:56:42

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 16:27:49
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 16:27:49
	(b) (4)	
Data point term sent to Coder	System	19 Feb 2021 16:26:50
User entered 'amlodipine'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'hypertension'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '5'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'mg (mg)'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'un UNK 2015'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 16:26:45
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 16:26:45
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 16:26:45
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 16:26:39
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'un Jul 2020'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
User entered '1'	(b) (4), (b) (6) System	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
User entered '1'	(b) (4), (b) (6) System	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:45
User entered '804 (804)'	(b) (4), (b) (6) System	19 Feb 2021 16:26:39

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: HIGH-CEILING DIURETICS, ATC: SULFONAMIDES, PLAIN, PRODUCT: FUROSEMIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 16:28:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 16:28:51
Data point term sent to Coder	System	19 Feb 2021 16:27:51
User entered 'furosemide'	(b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'congestive heart failure'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '40'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:25:50
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' answered with 'Always be on medication' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:28:22
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved. Per DM CLR: The corresponding recorded AE does not show 'ConMed Administered' for Action Taken. Please update Action Taken for AE as appropriate.' (Site from DM).	(b) (4), (b) (6)	07 Mar 2021 00:26:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '14 Sep 2020'	(b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Feb 2021 16:27:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC GENERALIZED PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 18:19:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:09:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 04:09:47
Data point term sent to Coder	System	01 Apr 2021 13:28:00
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC GENERALIZED PAIN should be recorded, and update con med indication or provide clarification. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:27:31
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 13:27:24
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening CHRONIC GENERALIZED PAIN should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 09:28:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:58:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 11:58:32

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US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
	(b) (4)	
Data point term sent to Coder	System	01 Mar 2021 14:45:12
User entered 'potassium chloride'	(b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:19:40
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	01 Apr 2021 13:27:24
User entered 'congestive heart failure' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 13:27:24
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'chronic generalized pain'	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '40'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:06:52
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Mar 2021 01:30:14
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 15:30:18
Signature has been broken.	(b) (4), (b) (6)	16 Mar 2021 15:30:11
User entered 'Other (OTHER)' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:30:11
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:02:16
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:06:52
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 15:30:11
User entered 'mEq' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Mar 2021 15:30:11
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '14 Sep 2020'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Mar 2021 14:44:27

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Mar 2021 14:45:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Mar 2021 14:45:51
Data point term sent to Coder	System	01 Mar 2021 14:45:13
User entered 'gabapentin'	(b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'chronic generalized pain'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '400'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:49:49

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Mar 2021 14:44:58

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:49:49

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:39
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:38:12
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	10 Nov 2020 20:38:10

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per source date of procedure is 10Sep20. Please confirm with source and update.' (Site from CRA).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 17:05:12
Query 'Per source date of procedure is 10Sep20. Please confirm with source and update.' answered with 'date is correct. Source has been updated' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	13 Nov 2020 23:31:50
User opened query 'Per source date of procedure is 10Sep20. Please confirm with source and update.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:40:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:27
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:24
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	11 Nov 2020 13:06:42
User entered '10 Sep 2020'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:38:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Electrocardiogram' reason for change:	Shanice Bennett (b) (4)	10 Nov 2020 20:39:16
Data Entry Error	(b) (4)	
User entered 'Congestive Heart Failure'	Shanice Bennett (b) (4)	10 Nov 2020 20:38:39
	(b) (4)	

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:38:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:49:49

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered empty.	Shanice Bennett (b) (4) (b) (4)	10 Nov 2020 20:38:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:49

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per source date of procedure is 10Sep20. Please confirm with source and update' (Site from CRA).	(b) (4), (b) (6)	13 Jan 2021 17:05:14
Query 'Per source date of procedure is 10Sep20. Please confirm with source and update' answered with 'date is correct. Source has been updated' (Site from CRA).	Shanice Bennett (b) (4)	13 Nov 2020 23:32:02
User opened query 'Per source date of procedure is 10Sep20. Please confirm with source and update' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 20:41:14
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered '11 Sep 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	11 Nov 2020 13:06:53
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:49

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Echocardiogram'	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:49

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered 'Adverse Event (AE)'	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39

US3022208

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:49:49

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:32:45
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 20:39:00
User entered empty.	Shanice Bennett (b) (4)	10 Nov 2020 20:39:39

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:49

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:56:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 19:26:03
User entered '10 Sep 2020'	Shanice Bennett (b) (4)	12 Oct 2020 18:10:47
	(b) (4)	

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:56:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' (Site from DM).	(b) (4)	
Query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:53:34
Query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:49:19
User entered 'SAE (specify) (SAE)' reason for change: Per Query Resolution	Morgan Deal (b) (4)	23 Nov 2020 18:49:12
User opened query 'Per CDM Re-query: it appears IP discontinuation was due to an SAE. Please update to SAE (Specify)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:35:31
Query 'Per CDM Re-Query: please record as 'SAE (Specify) and record Other Specify field with record number only (i.e. AE #1, etc.)' canceled (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:32:08
User opened query 'Per CDM Re-Query: please record as 'SAE (Specify) and record Other Specify field with record number only (i.e. AE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:05:48
User closed query 'Per CDM: Kindly clarify the reason for dosing discontinuation since on the AE page SAE #1 of CONGESTIVE HEART FAILURE is recorded as IP withdrawn. Review and reconcile Dosing discontinuation and AE pages as appropriate as per PI discretion. If the reason is SAE, ensure the SAE record number is recorded in the other specify field. ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:00:07
Query 'Per CDM: Kindly clarify the reason for dosing discontinuation since on the AE page SAE #1 of CONGESTIVE HEART FAILURE is recorded as IP withdrawn. Review and reconcile Dosing discontinuation and AE pages as appropriate as per PI discretion. If the reason is SAE, ensure the SAE record number is recorded in the other specify field. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4)	20 Nov 2020 16:09:29
DataPoint Un-verified.	(b) (4)	
	Shanice Bennett (b) (4)	20 Nov 2020 16:09:22
	(b) (4)	

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:49

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
User entered 'AE (specify) (ADVERSE EVENT)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:09:22
User opened query 'Per CDM: Kindly clarify the reason for dosing discontinuation since on the AE page SAE #1 of CONGESTIVE HEART FAILURE is recorded as IP withdrawn. Review and reconcile Dosing discontinuation and AE pages as appropriate as per PI discretion. If the reason is SAE, ensure the SAE record number is recorded in the other specify field. ' (Site from DM).	(b) (4), (b) (6)	20 Nov 2020 11:28:48
User closed query 'Per CDM: Primary reason for dosing discontinuation = Due to SARS-COV-2. Please note that the Covid-19 Assessment folder is not completed and there is no record of COVID-19 diagnosis on the AE page. Please review, reconcile and update as appropriate, else provide clarification in a query response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	16 Nov 2020 09:48:21
Query 'Per CDM: Primary reason for dosing discontinuation = Due to SARS-COV-2. Please note that the Covid-19 Assessment folder is not completed and there is no record of COVID-19 diagnosis on the AE page. Please review, reconcile and update as appropriate, else provide clarification in a query response. Thank you. ' answered with 'yes because she was diagnosed at the hospital. NO visit needed due to no symptoms' (Site from DM).	Shanice Bennett (b) (4)	13 Nov 2020 21:40:56
User opened query 'Per CDM: Primary reason for dosing discontinuation = Due to SARS-COV-2. Please note that the Covid-19 Assessment folder is not completed and there is no record of COVID-19 diagnosis on the AE page. Please review, reconcile and update as appropriate, else provide clarification in a query response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 13:02:07
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:26:03
User entered 'Due to SARS-COV-2 (COVID)'	Shanice Bennett (b) (4)	12 Oct 2020 18:10:47

US3022208

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:49:49

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:56:55
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User closed query 'Per CDM: Please record the record line number per CCGs without details (i.e. AE#1 SAE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 10:53:46
Query 'Per CDM: Please record the record line number per CCGs without details (i.e. AE#1 SAE #1, etc.)' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4)	23 Nov 2020 18:49:23
User entered 'SAE #1' reason for change: Per Query Resolution	Morgan Deal (b) (4)	23 Nov 2020 18:49:12
User opened query 'Per CDM: Please record the record line number per CCGs without details (i.e. AE#1 SAE #1, etc.)' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 01:34:46
Query 'Per CDM: update noted; however pleas consider recording as AE #1 per CCGs and remove details ' canceled (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:04:03
User opened query 'Per CDM: update noted; however pleas consider recording as AE #1 per CCGs and remove details ' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 22:03:23
DataPoint Un-verified.	Shanice Bennett (b) (4)	20 Nov 2020 16:09:22
User entered '#1 of CONGESTIVE HEART FAILUR' reason for change: Data Entry Error	Shanice Bennett (b) (4)	20 Nov 2020 16:09:22
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 19:26:03
User closed query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Oct 2020 18:10:51
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	12 Oct 2020 18:10:51
User opened query 'Primary reason for dosing discontinuation is not AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is provided. Please correct.' (Site from System).	System	12 Oct 2020 18:10:47
User entered 'test positive for COVID-19'	Shanice Bennett (b) (4)	12 Oct 2020 18:10:47

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '9'	(b) (4)	
User entered '8'	System	03 Feb 2021 19:41:28
User entered '7'	System	08 Dec 2020 14:49:32
User entered '6'	System	04 Dec 2020 13:43:46
User entered '5'	System	24 Nov 2020 00:13:37
User entered '4'	System	16 Nov 2020 13:45:50
User entered '3'	System	11 Nov 2020 20:16:11
User entered '2'	System	08 Oct 2020 16:47:15
User entered '1'	System	05 Oct 2020 13:01:46
	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '9'	(b) (4)	
User entered '8'	System	03 Feb 2021 19:41:28
User entered '7'	System	08 Dec 2020 14:49:32
User entered '6'	System	04 Dec 2020 13:43:46
User entered '5'	System	24 Nov 2020 00:13:37
User entered '4'	System	16 Nov 2020 13:45:50
User entered '3'	System	11 Nov 2020 20:16:11
User entered '2'	System	08 Oct 2020 16:47:15
User entered '1'	System	05 Oct 2020 13:01:46
	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered '15/Sep/2020 10:34'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '9'	(b) (4)	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered '05/Oct/2020 09:01'	System	05 Oct 2020 13:01:46

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 16:46:58
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 13:01:46

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '9'	(b) (4)	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered '08/Oct/2020 16:47'	System	08 Oct 2020 16:47:15

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 20:15:53
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 18:36:26
User entered 'I'	(b) (4), (b) (6)	08 Oct 2020 16:47:15

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '9'	System	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '11/Nov/2020 20:16'	(b) (4) System	11 Nov 2020 20:16:11

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Nov 2020 13:45:41
User entered 'I'	(b) (4), (b) (6)	11 Nov 2020 20:16:11

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '9'	System	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '16/Nov/2020 08:45'	(b) (4) System	16 Nov 2020 13:45:50

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	24 Nov 2020 00:13:20
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 13:45:50

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '9'	System	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '23/Nov/2020 19:13'	(b) (4) System	24 Nov 2020 00:13:37

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	04 Dec 2020 13:43:37
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 00:13:37

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '9'	(b) (4)	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '04/Dec/2020 13:43'	(b) (4) System	04 Dec 2020 13:43:46

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	08 Dec 2020 14:49:18
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 13:43:46

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '9'	(b) (4)	
User entered '8'	System	03 Feb 2021 19:41:28
User entered '7'	System	08 Dec 2020 14:49:32
User entered '6'	System	04 Dec 2020 13:43:46
User entered '5'	System	24 Nov 2020 00:13:37
User entered '4'	System	16 Nov 2020 13:45:50
User entered '3'	System	11 Nov 2020 20:16:11
User entered '2'	System	08 Oct 2020 16:47:15
User entered '1'	System	05 Oct 2020 13:01:46
	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '08/Dec/2020 14:49'	(b) (4) System	08 Dec 2020 14:49:32

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:41:47
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 14:49:32

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'USA-US051-2020-MRNA-1273-P301000003'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Yes (Y)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'No (N)'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Paul'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Bradley'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '340 Eisenhower Dr.'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'Savannah'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered 'GA'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:33:55
User entered '31406'	System	15 Sep 2020 14:31:39

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 18:36:26
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 13:01:37
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:48:34
User entered 'US' (non-conformant).	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 09 Jun 2021 14:49:49

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
	(b) (4)	
User entered '9'	System	03 Feb 2021 19:41:28
User entered '8'	System	08 Dec 2020 14:49:32
User entered '7'	System	04 Dec 2020 13:43:46
User entered '6'	System	24 Nov 2020 00:13:37
User entered '5'	System	16 Nov 2020 13:45:50
User entered '4'	System	11 Nov 2020 20:16:11
User entered '3'	System	08 Oct 2020 16:47:15
User entered '2'	System	05 Oct 2020 13:01:46
User entered '1'	System	15 Sep 2020 14:34:02

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:49:49

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
User entered '03/Feb/2021 14:41'	(b) (4) System	03 Feb 2021 19:41:28

US3022208

Folder: SAE USA-US051-2020-MRNA-1273-P301000003

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:49:49

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:29:45
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	03 Feb 2021 19:41:47
User entered 'I'	(b) (4), (b) (6)	03 Feb 2021 19:41:28