

US3222032 (Prod: Accel Research Site - Avail - ERN-PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:04:31

All time stamps listed in this document are displayed in GMT

US3222032

Form: Participant Creation

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

[Participant ID](#)

US3222032

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

US3222032

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 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

US3222032

Folder: Screening

Form: Demographics

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Date of Birth (MMM yyyy)	(b) (6) 1947
Age	73
Age Units	YEARS
Age (Derived)	73
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	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 16 Feb 2021 19:19:06

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Date of Informed Consent (<i>dd MMM yyyy</i>)	7 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 16 Feb 2021 19:19:06

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Were any significant conditions reported?

Yes ☒
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	CHRONIC BACK PAIN
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 (4)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	HYPERCHOLESTEROLEMIA
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 (5)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	HYPERTENSION
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 (6)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	HYPOTHYROIDISM
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Start Year (derived)	1981
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	OSTEOARTHRITIS-KNEES - NO OFFICIAL DX AT THIS TIME.
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3222032

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	TUBAL LIGATION
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Condition	MENORRHAGIA
Start date (dd MMM yyyy)	UN UNK 2002
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	7 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	13:55 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 13:55
Height (<i>xxx.x</i>)	157.5 cm
Weight (<i>xxx.x</i>)	76.3 kg
BMI (<i>xxx.x</i>)	30.75838 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 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) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*) 7 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 1998

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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 MISSIONARY

Location and Living Circumstances Risk (check all that apply)

No Risk Identified True

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 16 Feb 2021 19:19:06

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 185085

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 ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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)	7 AUG 2020
Time of assessment (00:00-23:59)	14:05 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 14:05
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 AUG 2020
Time of assessment (00:00-23:59)	15:36 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 15:36
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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) 7 AUG 2020

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

Treatment Date and Time (derived) 7 AUG 2020 15:00

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 AUG 2020
Collection time (00:00-23:59)	14:20 (24 HR)
Collection date and time (derived)	7 AUG 2020 14:20

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:24	7 AUG 2020 14:24
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 AUG 2020 15:33

PC Open Date & Time

07 AUG 2020 15:20

PC Close Date & Time

07 AUG 2020 17:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐
No ☒

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

PC Time Stamp	07 AUG 2020 19:20
PC Open Date & Time	07 AUG 2020 18:45
PC Close Date & Time	08 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 12:03

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 AUG 2020 12:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 15:31

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

101.9 °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

11 AUG 2020 12:03

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

13 AUG 2020 11:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

13 AUG 2020 12:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

07 AUG 2020 15:34

PC Open Date & Time

07 AUG 2020 15:20

PC Close Date & Time

07 AUG 2020 17:50

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

08 AUG 2020 10:28

PC Open Date & Time

07 AUG 2020 18:45

PC Close Date & Time

08 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 12:04

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

10 AUG 2020 15:32

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:04

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

13 AUG 2020 11:21

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

13 AUG 2020 12:01

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 15:35
PC Open Date & Time	07 AUG 2020 15:20
PC Close Date & Time	07 AUG 2020 17:50

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 10:29
PC Open Date & Time	07 AUG 2020 18:45
PC Close Date & Time	08 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

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 ☒

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 12:04
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

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 ☒

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:07
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 15:32
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

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)

63 of 2091

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

65 of 2091

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

67 of 2091

EAB) (1725)

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:01
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3222032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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)	4 SEP 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 14:25
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 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)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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)	4 SEP 2020
Time of assessment (00:00-23:59)	15:38 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:38
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3222032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

4 SEP 2020

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

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

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) 4 SEP 2020

What was the treatment time? (00:00-23:59) 15:07 (24 HR)

Treatment Date and Time (derived) 4 SEP 2020 15:07

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

US3222032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 SEP 2020
Collection time (00:00-23:59)	15:00 (24 HR)
Collection date and time (derived)	4 SEP 2020 15:00

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Collection date (dd MMM yyyy)			4 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:04	4 SEP 2020 15:04
Nasopharyngeal Swab 2	No		

US3222032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:06

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

04 SEP 2020 15:56

PC Open Date & Time

04 SEP 2020 15:27

PC Close Date & Time

04 SEP 2020 17:57

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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 100.3 °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	05 SEP 2020 10:13
PC Open Date & Time	04 SEP 2020 18:52
PC Close Date & Time	05 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 09:58

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 14:39

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

99.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 12:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 09:57

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 17:26

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

04 SEP 2020 15:56

PC Open Date & Time

04 SEP 2020 15:27

PC Close Date & Time

04 SEP 2020 17:57

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

05 SEP 2020 10:13

PC Open Date & Time

04 SEP 2020 18:52

PC Close Date & Time

05 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 09:59

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 14:40

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

07 SEP 2020 12:48

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 09:58

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

09 SEP 2020 12:02

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

10 SEP 2020 17:26

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:57
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PC Open Date & Time	04 SEP 2020 15:27
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PC Close Date & Time	04 SEP 2020 17:57
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US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

No ☒

Yes ☐

PC Time stamp	05 SEP 2020 10:14
PC Open Date & Time	04 SEP 2020 18:52
PC Close Date & Time	05 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

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 ☒

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 09:59
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

		Yes <input type="checkbox"/>
PC Time stamp	06 SEP 2020 14:40	
PC Open Date & Time	06 SEP 2020 12:00	
PC Close Date & Time	07 SEP 2020 11:59	

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

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 ☒

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:48
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

109 of 2091

EAB) (1725)

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 09:58
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

111 of 2091

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:03
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

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)

113 of 2091

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 17:26
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3222032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:19:07

Generated On: 09 Jun 2021 16:04:31

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Feb 2021 19:19:07

Generated On: 09 Jun 2021 16:04:31

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) _____

US3222032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Feb 2021 19:19:07

Generated On: 09 Jun 2021 16:04:31

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.

US3222032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 19:19:07

Generated On: 09 Jun 2021 16:04:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 OCT 2020
Collection time (00:00-23:59)	12:40 (24 HR)
Collection date and time (derived)	6 OCT 2020 12:40

US3222032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:07

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

07 OCT 2020 11:13:25

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

14 OCT 2020 08:50:16

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 OCT 2020 17:59:50

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 NOV 2020 12:01:07

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 NOV 2020 00:50:54
Patient Cloud Open Date & Time	11 NOV 2020 00:01
Patient Cloud Close Date & Time	15 NOV 2020 23:59

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 106
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"/>

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 08:11:08

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

30 NOV 2020 12:00:03

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 07:59:08

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 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"/>
Date and time of submission	13 DEC 2020 12:44:15
Patient Cloud Open Date & Time	13 DEC 2020 00:01
Patient Cloud Close Date & Time	17 DEC 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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 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"/>
Date and time of submission	20 DEC 2020 08:21:08
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 04:09:30

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

03 JAN 2021 08:05:39

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 10:37:00

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 12:00:56
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

27 JAN 2021 14:33:44

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 08:16:55

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

07 FEB 2021 12:16:41

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 00:27:26
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

21 FEB 2021 08:17:50

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

01 MAR 2021 18:39:48

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

07 MAR 2021 22:06:47

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

16 MAR 2021 13:08:10

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

21 MAR 2021 00:08:43

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 09:40:51

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

05 APR 2021 19:29:23

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 APR 2021 08:10:28
Patient Cloud Open Date & Time	11 APR 2021 00:01
Patient Cloud Close Date & Time	15 APR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

20 APR 2021 13:06:23

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 APR 2021 13:02:23

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

Date and time of submission

02 MAY 2021 23:32:03

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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="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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	16 DEC 2021 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 509

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

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

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

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

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

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

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

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 JAN 2022 00:01
Patient Cloud Close Date & Time	13 JAN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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°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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 APR 2022 00:01
Patient Cloud Close Date & Time	14 APR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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°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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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°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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 <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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2022 00:01
Patient Cloud Close Date & Time	18 AUG 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	02 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 OCT 2022 00:01
Patient Cloud Close Date & Time	13 OCT 2022 23:59

US3222032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:04:31

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		01 MAR 2021 18:39:07

US3222032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 21:06:17

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:06:17

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 21:06:17

Generated On: 09 Jun 2021 16:04:31

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

Visit date (dd MMM yyyy)	03 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
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US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 07 Apr 2021 17:29:05

Generated On: 09 Jun 2021 16:04:31

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) _____

US3222032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Mar 2021 21:06:17

Generated On: 09 Jun 2021 16:04:31

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.

US3222032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 21:06:17

Generated On: 09 Jun 2021 16:04:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 MAR 2021
Collection time (00:00-23:59)	11:35 (24 HR)
Collection date and time (derived)	03 MAR 2021 11:35

US3222032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 21:06:17

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 07 Apr 2021 17:29:05

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 07 Apr 2021 17:29:05

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 15:52:57

Generated On: 09 Jun 2021 16:04:31

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3222032

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:52:57

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3222032

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

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

US3222032

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3222032

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:04:31

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"/>

US3222032

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:04:31

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3222032

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

Form: Visit Date

Data signed: (b) (4) 16 Feb 2021 19:19:05

Generated On: 09 Jun 2021 16:04:31

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

Visit date (dd MMM yyyy)	20 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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US3222032

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 17:11:24

Generated On: 09 Jun 2021 16:04:31

Date of updated informed consent (dd MMM yyyy) 20 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 20 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3222032

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00-23:59)	11:40 (24 HR)
Collection date and time (derived)	20 JAN 2021 11:40

US3222032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 JAN 2021
Collection time (00:00 - 23:59)	11:43
Collection Date and Time (derived)	20 JAN 2021 11:43

US3222032

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

AEID	USA-US104-2020-MRNA-1273-P30 1000025
Adverse event	ELEVATED LIVER ENZYMES
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)	13 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	13 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	21 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

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 <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

I WAS INFORMED BY THE
SAFETY CALL STAFF ON
14/DEC/2020 @ 13:58 THAT THIS
SUBJECT WAS HOSPITALIZED
FOR AN UNSPECIFIED
ELEVATED LIVER ENZYMES
DURING THEIR SAFETY CALL
WITH HER. SHE WILL CALL ME
AND LET ME KNOW WHEN SHE
IS DISCHARGED AND I WILL
REQUEST RECORDS THEN.

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

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

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

Yes ☒

No ☐

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

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

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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US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 1980	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication ATORVASTATIN

Prophylaxis Yes ☒
No ☐

Indication HYPERCHOLESTEROLEMIA

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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US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)		01 JAN 1980
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"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication CARVEDILOL

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)		01 JAN 1980
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"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication FLEXERIL

Prophylaxis Yes ☒
No ☐

Indication CHRONIC BACK PAIN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 1980	
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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication GABAPENTIN

Prophylaxis Yes ☒
No ☐

Indication CHRONIC BACK PAIN

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 2010	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☒
No ☐

Indication HYPOTHYROIDISM

Dose per administration 200

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

If dose unit is Other, specify MCG

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 6 DAYS PER WEEK

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 1981	
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"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication LOSARTAN

Prophylaxis Yes ☒
No ☐

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)		01 JAN 1980
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"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication MORPHINE

Prophylaxis Yes ☒
No ☐

Indication CHRONIC BACK PAIN

Dose per administration 15

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication OMEPROZOLE

Prophylaxis Yes ☒
No ☐

Indication ACID REFLUX

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication OXYCODONE

Prophylaxis Yes ☒
No ☐

Indication CHRONIC BACK PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Name of Medication VENLAFAXINE

Prophylaxis Yes ☒
No ☐

Indication ANXIETY

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

	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)	01 JAN 2000	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3222032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 16 Feb 2021 18:14:21

Generated On: 09 Jun 2021 16:04:31

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:04:31

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:04:31

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 ☐

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 13:34:35

Generated On: 09 Jun 2021 16:04:31

SAEID	USA-US104-2020-MRNA-1273-P301000025
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 13:34:35

Generated On: 09 Jun 2021 16:04:31

SAEID	USA-US104-2020-MRNA-1273-P301000025
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/DEC/2020 13:48
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

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 13:34:35

Generated On: 09 Jun 2021 16:04:31

SAEID	USA-US104-2020-MRNA-1273-P301000025
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/DEC/2020 12:20
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

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 13:34:35

Generated On: 09 Jun 2021 16:04:31

SAEID	USA-US104-2020-MRNA-1273-P301000025
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/APR/2021 08:20
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

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 13:34:35

Generated On: 09 Jun 2021 16:04:31

SAEID	USA-US104-2020-MRNA-1273-P301000025
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	13/APR/2021 11:52
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 13:34:35

Generated On: 09 Jun 2021 16:04:31

SAEID	USA-US104-2020-MRNA-1273-P301000025
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	BRUCE
Investigator's Last Name	RANKIN
Site Address: Street	860 PEACHWOOD AVE
Site Address: City	DELAND
Site Address: State	
Site Address: Postal Code	32720
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	23/APR/2021 10:38
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

US3222032 (Prod: Accel Research Site - Avail - ERN-PPDS)

US3222032

Form: Participant Creation

Generated On: 09 Jun 2021 16:04:31

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'US3222032'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) [REDACTED]	07 Aug 2020 17:44:19

US3222032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:36:49

US3222032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:44:20

US3222032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:36:49

US3222032

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'SCRN'	System	07 Aug 2020 18:36:49

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered (b) (6) 1947'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:44:21

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '73'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'YEARS'	System	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '73'	System	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Female (F)'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'I'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

Black

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:04:31

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:10

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Aug 2020'	System	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2020'	System	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Amendment 1 (1)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:03

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 17:44:20

US3222032

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:04:31

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'I'	System	07 Aug 2020 19:05:04

US3222032

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:05:04

US3222032

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:04:31

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:10:36

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
Data point term sent to Coder	System	07 Aug 2020 22:11:51
User entered 'acid reflux'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 2000'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2000'	System	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2000'	System	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:10:55

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
Data point term sent to Coder	System	07 Aug 2020 22:11:51
User entered 'anxiety'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 2000'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2000'	System	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2000'	System	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:11:08

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
Data point term sent to Coder	System	07 Aug 2020 22:11:51
User entered 'chronic back pain'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1980'	System	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1980'	System	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:11:29

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:12:18
Data point term sent to Coder	System	07 Aug 2020 22:11:51
User entered 'hypercholesterolemia'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1980'	System	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1980'	System	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:11:47

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
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)	19 Oct 2020 12:58:24
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 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:28:17
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)	10 Sep 2020 13:01:16
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)	07 Aug 2020 22:14:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:14:19
Data point term sent to Coder	System	07 Aug 2020 22:12:52
User entered 'hypertension'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1980'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1980'	System	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1980'	System	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:12:05

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
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)	19 Oct 2020 13:00:28
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 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:28:37
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)	10 Sep 2020 13:01:37
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:14:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:14:19
Data point term sent to Coder	System	07 Aug 2020 22:12:52
User entered 'hypothyroidism'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1981'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1981'	System	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1981'	System	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:12:22

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Nervous system disorders, HLGT: Mental impairment disorders, HLT: Memory loss (excl dementia), PT: Amnesia, LLT: Memory loss - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:14:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:14:19
Data point term sent to Coder	System	07 Aug 2020 22:12:52
User entered 'memory loss'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 2018'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2018'	System	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2018'	System	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:12:38

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knee - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:02:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 14:02:58
Data point term sent to Coder	System	28 Oct 2020 13:04:07
Coding entries removed.	Albert Garcia (b) (4)	28 Oct 2020 13:03:27
User entered 'OSTEOARTHRITIS-KNEES - NO OFFICIAL DX AT THIS TIME.' reason for change:	Albert Garcia (b) (4)	28 Oct 2020 13:03:27
Data Entry Error	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis knees - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:44:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:44:24
Data point term sent to Coder	System	07 Aug 2020 22:13:53
User entered 'osteoarthritis-knees'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:04
	(b) (4)	

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 2019'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2019'	System	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2019'	System	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:13:04

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
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)	07 Aug 2020 22:14:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:14:20
Data point term sent to Coder	System	07 Aug 2020 22:13:54
User entered 'postmenopausal'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1998'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1998'	System	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1998'	System	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	07 Aug 2020 22:13:20

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:14:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 22:14:20
Data point term sent to Coder	System	07 Aug 2020 22:13:54
User entered 'tubal ligation'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1986'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1986'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1986'	System	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1986'	System	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 1986'	System	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1986'	System	07 Aug 2020 22:13:38

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 13:02:51
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	07 Oct 2020 11:34:46
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 13:02:36
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:16:21
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Aug 2020 22:16:21
Data point term sent to Coder	System	07 Aug 2020 22:14:55
User entered 'hysterectomy'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 2005'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 2005'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2005'	System	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2005'	System	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2005'	System	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2005'	System	07 Aug 2020 22:13:56

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Menstrual cycle and uterine bleeding disorders, HLT: Menstruation with increased bleeding, PT: Menorrhagia, LLT: Menorrhagia - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 11:40:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Oct 2020 11:40:48
Data point term sent to Coder	System	07 Oct 2020 11:35:51
User entered 'MENORRHAGIA'	Albert Garcia (b) (4)	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN UNK 2002'	Albert Garcia (b) (4)	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Albert Garcia (b) (4)	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Albert Garcia (b) (4)	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN UNK 2005'	Albert Garcia (b) (4)	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Albert Garcia (b) (4)	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2002'	System	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2002'	System	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2005'	System	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2005'	System	07 Oct 2020 11:35:09

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Surgical and medical procedures, HLGT: Hepatobiliary therapeutic procedures, HLT: Biliary tract and gallbladder therapeutic procedures, PT: Cholecystectomy, LLT: Cholecystectomy - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:40:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:40:48
Data point term sent to Coder	System	17 Nov 2020 17:39:45
User entered 'CHOLECYSTECTOMY'	Amber Vasquez (b) (4)	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN Jan 2020'	Amber Vasquez (b) (4)	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN Jan 2020'	Amber Vasquez (b) (4)	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2020'	System	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2020'	System	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2020'	System	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2020'	System	17 Nov 2020 17:39:44

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:41:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Nov 2020 17:41:48
Data point term sent to Coder	System	17 Nov 2020 17:40:46
User entered 'CHOLESYSTITIS'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN Jan 2020'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN Jan 2020'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2020'	System	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2020'	System	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Jan 2020'	System	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2020'	System	17 Nov 2020 17:40:05

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 18:21:16
Query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' answered with 'CONDICTION IS NOT TREATED. ' (Site from DM).	Albert Garcia (b) (4) (b) (4)	02 Dec 2020 14:26:52
User opened query 'Per CDM: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected?. Please review and if applicable add a Con Med or, if CM is already recorded, please provide log line number ensuring indication matches with this condition.' (Site from DM).	(b) (4), (b) (6)	26 Nov 2020 13:34:18
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:56:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 17:56:48
Data point term sent to Coder	System	17 Nov 2020 17:40:46
User entered 'ABDOMINAL PAIN'	Amber Vasquez (b) (4) (b) (4)	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'UN Apr 2020'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'Apr 2020'	System	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '2020'	System	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	17 Nov 2020 17:40:22

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '13:55'	Amber Vasquez (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '7 Aug 2020 13:55'	System	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '157.5' cm	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:14:52
DataPoint set to visible.	(b) (4) System	07 Aug 2020 19:05:04

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '76.3' kg	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:14:52
DataPoint set to visible.	(b) (4) System	07 Aug 2020 19:05:04

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
Amendment Manager: User entered '30.75838'	System	16 Sep 2020 23:47:43
User entered '30.8'	System	07 Aug 2020 22:14:52
DataPoint set to visible.	System	07 Aug 2020 19:05:04

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'kg/m2'	System	07 Aug 2020 22:14:52
DataPoint set to visible.	System	07 Aug 2020 19:05:04

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:40:52
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:03
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:17:32
User entered '36.9' C	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty; reason for change Data Entry Error	(b) (4)	
	Albert Garcia (b) (4)	15 Sep 2020 19:03:03
User entered 'Oral (Oral)'	(b) (4)	
	Amber Vasquez (b) (4)	07 Aug 2020 22:14:52
	(b) (4)	

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:40:54
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:16
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:03
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:17:41
User entered '64'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'bpm'	System	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:40:56
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:20
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:03
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:17:47
User entered '16'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'breaths/min'	System	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:41:00
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:23
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:03
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:17:52
User entered '140'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'mmHg'	System	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	21 Sep 2020 16:41:02
Query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:26
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:03:03
User opened query 'Per CDM: As per CCG Pages 15-16, 'ND' should be entered in TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP at Screening Visit. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 12:17:57
User entered '75'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'mmHg'	System	07 Aug 2020 22:14:52

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54

US3222032

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54

US3222032

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:14:57

US3222032

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:29:45
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	04 Sep 2020 19:51:53
User entered '7 Aug 2020'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:14:57

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'un UNK 1998'	Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:04:31

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:15:29

US3222032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

Form: Risk of Exposure

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Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

Form: Risk of Exposure

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[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

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Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

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Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'missionary'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'I'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '0'	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:04:31

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:16:26

US3222032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:23

US3222032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:23

US3222032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	07 Aug 2020 18:37:23

US3222032

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'VISIT1'	System	07 Aug 2020 18:37:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:24:24

US3222032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 02:55:23
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:55:23
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 18:24:24
User entered '185085' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:24:24

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Folder: Visit 1 Day 1

Form: Randomization

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[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 18:24:24

US3222032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

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)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	07 Aug 2020 22:38:12
User entered 'No (N)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:09

US3222032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

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)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)' reason for change: Data Entry Error	Jennifer Dittman (b) (4)	07 Aug 2020 22:38:12
User entered 'No (N)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:09

US3222032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:09

US3222032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:09

US3222032

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:04:31

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:09

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:10:24
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 19:02:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:02:13
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:19
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:19
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'nd' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:38:30
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:44
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:44
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:58
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:48:01
User entered '157.5' cm	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:10:27
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 19:02:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:02:13
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:30
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:30
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:38:37
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:49
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:49
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:01:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:48:07
User entered '76.3' kg	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:10:24
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 19:02:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:02:13
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:19
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:19
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'nd' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:38:30
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:44
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:44
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:58
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:48:01
User entered '157.5' cm	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:10:27
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 19:02:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:02:13
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:30
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:30
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:38:37
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:49
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:49
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:01:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:48:07
User entered '76.3' kg	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '14:05'	(b) (4) Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '7 Aug 2020 14:05'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '36.8' C	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '62'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'bpm'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '16'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'breaths/min'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '138'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '72'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:31

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:10:24
Query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 19:02:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:02:13
User opened query 'Per CDM: Thanks for your response. Please update the 'HEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:19
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:19
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'nd' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:38:30
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:44
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:44
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:58
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify".' (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:48:01
User entered '157.5' cm	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:04:31

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Sep 2020 09:10:27
Query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' answered by data change (Site from DM).	System	15 Sep 2020 19:02:13
User entered missing code ND - Not Done; reason for change Data Entry Error	Albert Garcia (b) (4) (b) (4)	15 Sep 2020 19:02:13
User opened query 'Per CDM: Thanks for your response. Please update the 'WEIGHT' field accordingly.' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:30
User closed query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	10 Sep 2020 14:37:30
Query 'Per CDM: Per CCGs data is required please review and update accordingly ' answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:38:37
User opened query 'Per CDM: Per CCGs data is required please review and update accordingly ' (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:49
User closed query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	04 Sep 2020 17:54:49
Query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". answered with 'ND' (Site from DM).	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:01:07
User entered empty; reason for change Data Entry Error	Amber Vasquez (b) (4) (b) (4)	01 Sep 2020 21:00:49
User opened query "Per CDM: Per CCGs pages 15-16, "Height and Weight" should be marked as "ND." Please review and update else clarify". (Site from DM).	(b) (4), (b) (6)	28 Aug 2020 17:48:07
User entered '76.3' kg	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	10 Aug 2020 07:10:17
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'correct as is' (Site from System).	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:18:04
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 22:17:52
User entered '15:36'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '7 Aug 2020 15:36'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '36.9' C	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '60'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'bpm'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '16'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'breaths/min'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '140'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '85'	Amber Vasquez (b) (4)	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	07 Aug 2020 22:17:52

US3222032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	07 Aug 2020 22:18:11

US3222032

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:18:11

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

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)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '15:00'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered '7 Aug 2020 15:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'ONCE'	System	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 19:07:32

US3222032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	07 Aug 2020 22:18:28

US3222032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:18:28

US3222032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '14:20'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:18:28

US3222032

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered '7 Aug 2020 14:20'	System	07 Aug 2020 22:18:28

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '7 Aug 2020'	Amber Vasquez (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '14:24'	(b) (4) Amber Vasquez (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered '7 Aug 2020 14:24'	System	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered empty.	System	07 Aug 2020 22:18:37

US3222032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	07 Aug 2020 22:18:41

US3222032

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	07 Aug 2020 22:18:41

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:32:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '6d2d2328-7221-43f0-a444-62502df71726' User entered 'Yes (Y)'	System	07 Aug 2020 19:33:20
	System	07 Aug 2020 19:33:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:33:04', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '6d2d2328-7221-43f0-a444-62502df71726' User entered '98.4'	System	07 Aug 2020 19:33:20
	System	07 Aug 2020 19:33:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:33:13', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '6d2d2328-7221-43f0-a444-62502df71726'	System	07 Aug 2020 19:33:20
User entered 'No (N)'	System	07 Aug 2020 19:33:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:33:19', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '6d2d2328-7221-43f0-a444-62502df71726' User entered '07 Aug 2020 15:33'	System	07 Aug 2020 19:33:20
	System	07 Aug 2020 19:33:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 15:20'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 17:50'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T19:19:04', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '93025f22-643b-4a77-af92-b3767279e78d' User entered 'Yes (Y)'	System	07 Aug 2020 23:20:58
	System	07 Aug 2020 23:20:58

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T19:20:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '93025f22-643b-4a77-af92-b3767279e78d' User entered '97.4'	System	07 Aug 2020 23:20:58
	System	07 Aug 2020 23:20:58

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T19:20:31', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '93025f22-643b-4a77-af92-b3767279e78d' User entered 'No (N)'	System	07 Aug 2020 23:20:58
	System	07 Aug 2020 23:20:58

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T19:20:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '93025f22-643b-4a77-af92-b3767279e78d' User entered '07 Aug 2020 19:20'	System	07 Aug 2020 23:20:58
	System	07 Aug 2020 23:20:58

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 18:45'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 2'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a58fdacb-4e8c-423c-873a-e074dea1547c' User entered 'Yes (Y)'	System	08 Aug 2020 16:03:37
	System	08 Aug 2020 16:03:37

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:23', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a58fdacb-4e8c-423c-873a-e074dea1547c' User entered '98.4'	System	08 Aug 2020 16:03:37
	System	08 Aug 2020 16:03:37

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:27', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a58fdacb-4e8c-423c-873a-e074dea1547c'	System	08 Aug 2020 16:03:37
User entered 'No (N)'	System	08 Aug 2020 16:03:37

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a58fdacb-4e8c-423c-873a-e074dea1547c' User entered '08 Aug 2020 12:03'	System	08 Aug 2020 16:03:37
	System	08 Aug 2020 16:03:37

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 3'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:06:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd01d3a3f-8885-44ee-a6b2-0ea34f72ffd8' User entered 'Yes (Y)'	System	09 Aug 2020 16:07:03
	System	09 Aug 2020 16:07:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:06:48', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd01d3a3f-8885-44ee-a6b2-0ea34f72ffd8' User entered '98.4'	System	09 Aug 2020 16:07:03
	System	09 Aug 2020 16:07:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:06:53', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd01d3a3f-8885-44ee-a6b2-0ea34f72ffd8'	System	09 Aug 2020 16:07:03
User entered 'No (N)'	System	09 Aug 2020 16:07:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:01', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd01d3a3f-8885-44ee-a6b2-0ea34f72ffd8' User entered '09 Aug 2020 12:07'	System	09 Aug 2020 16:07:03
	System	09 Aug 2020 16:07:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 4'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:30:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '28e20d0e-6864-48ee-b7e7-f17dfbf90633'	System	10 Aug 2020 19:31:49
User entered 'Yes (Y)'	System	10 Aug 2020 19:31:49

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:31:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '28e20d0e-6864-48ee-b7e7-f17dfbf90633' User entered '97.8'	System	10 Aug 2020 19:31:49
	System	10 Aug 2020 19:31:49

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:31:36', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '28e20d0e-6864-48ee-b7e7-f17dfbf90633'	System	10 Aug 2020 19:31:49
User entered 'No (N)'	System	10 Aug 2020 19:31:49

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:31:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '28e20d0e-6864-48ee-b7e7-f17dfbf90633'	System	10 Aug 2020 19:31:49
User entered '10 Aug 2020 15:31'	System	10 Aug 2020 19:31:49

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 5'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:00:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6fa2c6f-353d-4b81-8b98-1fbe75cffcf7'	System	11 Aug 2020 16:03:05
User entered 'Yes (Y)'	System	11 Aug 2020 16:03:05

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:02:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6fa2c6f-353d-4b81-8b98-1fbe75cffcf7' User entered '101.9'	System	11 Aug 2020 16:03:05
	System	11 Aug 2020 16:03:05

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:02:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6fa2c6f-353d-4b81-8b98-1fbe75cffcf7'	System	11 Aug 2020 16:03:05
User entered 'No (N)'	System	11 Aug 2020 16:03:05

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:03:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6fa2c6f-353d-4b81-8b98-1fbe75cffcf7'	System	11 Aug 2020 16:03:05
User entered '11 Aug 2020 12:03'	System	11 Aug 2020 16:03:05

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 6'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:17:41', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3d5a5726-5fa8-47fc-9229-7b3a5d8a64b3' User entered 'Yes (Y)'	System	13 Aug 2020 15:21:03
	System	13 Aug 2020 15:21:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:20:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3d5a5726-5fa8-47fc-9229-7b3a5d8a64b3' User entered '98.3'	System	13 Aug 2020 15:21:03
	System	13 Aug 2020 15:21:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:20:48', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3d5a5726-5fa8-47fc-9229-7b3a5d8a64b3'	System	13 Aug 2020 15:21:03
User entered 'No (N)'	System	13 Aug 2020 15:21:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3d5a5726-5fa8-47fc-9229-7b3a5d8a64b3' User entered '13 Aug 2020 11:21'	System	13 Aug 2020 15:21:03
	System	13 Aug 2020 15:21:03

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 7'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b7fba690-81ea-4818-9e23-e02c379b9660' User entered 'Yes (Y)'	System	13 Aug 2020 16:01:20
	System	13 Aug 2020 16:01:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:04', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b7fba690-81ea-4818-9e23-e02c379b9660' User entered '98.3'	System	13 Aug 2020 16:01:20
	System	13 Aug 2020 16:01:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b7fba690-81ea-4818-9e23-e02c379b9660'	System	13 Aug 2020 16:01:20
User entered 'No (N)'	System	13 Aug 2020 16:01:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:11', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b7fba690-81ea-4818-9e23-e02c379b9660' User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:01:20
	System	13 Aug 2020 16:01:20

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:33:45', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8ee61720-de52-45a6-bee4-0d880db325a1' User entered 'None (1)'	System	07 Aug 2020 19:34:43
	System	07 Aug 2020 19:34:43

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:04', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8ee61720-de52-45a6-bee4-0d880db325a1' User entered 'No (N)'	System	07 Aug 2020 19:34:43
	System	07 Aug 2020 19:34:43

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:07', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8ee61720-de52-45a6-bee4-0d880db325a1' User entered 'No (N)'	System	07 Aug 2020 19:34:43
	System	07 Aug 2020 19:34:43

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8ee61720-de52-45a6-bee4-0d880db325a1' User entered 'None (1)'	System	07 Aug 2020 19:34:43
	System	07 Aug 2020 19:34:43

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:41', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8ee61720-de52-45a6-bee4-0d880db325a1' User entered '07 Aug 2020 15:34'	System	07 Aug 2020 19:34:43
	System	07 Aug 2020 19:34:43

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 15:20'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 17:50'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:27:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1d9a85e6-6ed0-46d9-94bd-52f34be5a986' User entered 'None (1)'	System	08 Aug 2020 14:28:07
	System	08 Aug 2020 14:28:07

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:27:39', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1d9a85e6-6ed0-46d9-94bd-52f34be5a986' User entered 'No (N)'	System	08 Aug 2020 14:28:07
	System	08 Aug 2020 14:28:07

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:27:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1d9a85e6-6ed0-46d9-94bd-52f34be5a986' User entered 'No (N)'	System	08 Aug 2020 14:28:07
	System	08 Aug 2020 14:28:07

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:27:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1d9a85e6-6ed0-46d9-94bd-52f34be5a986' User entered 'None (1)'	System	08 Aug 2020 14:28:07
	System	08 Aug 2020 14:28:07

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:03', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1d9a85e6-6ed0-46d9-94bd-52f34be5a986' User entered '08 Aug 2020 10:28'	System	08 Aug 2020 14:28:07
	System	08 Aug 2020 14:28:07

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 18:45'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 2'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7a7f7cb1-ea4a-4d21-b2a2-95bde4e3afc1' User entered 'None (1)'	System	08 Aug 2020 16:04:09
	System	08 Aug 2020 16:04:09

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7a7f7cb1-ea4a-4d21-b2a2-95bde4e3afc1' User entered 'No (N)'	System	08 Aug 2020 16:04:09
	System	08 Aug 2020 16:04:09

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:03:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7a7f7cb1-ea4a-4d21-b2a2-95bde4e3afc1' User entered 'No (N)'	System	08 Aug 2020 16:04:09
	System	08 Aug 2020 16:04:09

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:01', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7a7f7cb1-ea4a-4d21-b2a2-95bde4e3afc1' User entered 'None (1)'	System	08 Aug 2020 16:04:09
	System	08 Aug 2020 16:04:09

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:07', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7a7f7cb1-ea4a-4d21-b2a2-95bde4e3afc1' User entered '08 Aug 2020 12:04'	System	08 Aug 2020 16:04:09
	System	08 Aug 2020 16:04:09

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 3'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b25ee35b-1b07-4300-b147-fb43f71730f3' User entered 'None (1)'	System	09 Aug 2020 16:07:29
	System	09 Aug 2020 16:07:29

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:12', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b25ee35b-1b07-4300-b147-fb43f71730f3' User entered 'No (N)'	System	09 Aug 2020 16:07:29
	System	09 Aug 2020 16:07:29

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:16', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b25ee35b-1b07-4300-b147-fb43f71730f3' User entered 'No (N)'	System	09 Aug 2020 16:07:29
	System	09 Aug 2020 16:07:29

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:21', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b25ee35b-1b07-4300-b147-fb43f71730f3' User entered 'None (1)'	System	09 Aug 2020 16:07:29
	System	09 Aug 2020 16:07:29

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:25', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b25ee35b-1b07-4300-b147-fb43f71730f3' User entered '09 Aug 2020 12:07'	System	09 Aug 2020 16:07:29
	System	09 Aug 2020 16:07:29

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 4'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:31:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '307d9d6a-ee28-4330-9fe5-2dad0045c2ea' User entered 'None (1)'	System	10 Aug 2020 19:32:23
	System	10 Aug 2020 19:32:23

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:02', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '307d9d6a-ee28-4330-9fe5-2dad0045c2ea' User entered 'No (N)'	System	10 Aug 2020 19:32:23
	System	10 Aug 2020 19:32:23

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '307d9d6a-ee28-4330-9fe5-2dad0045c2ea' User entered 'No (N)'	System	10 Aug 2020 19:32:23
	System	10 Aug 2020 19:32:23

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '307d9d6a-ee28-4330-9fe5-2dad0045c2ea' User entered 'None (1)'	System	10 Aug 2020 19:32:23
	System	10 Aug 2020 19:32:23

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:21', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '307d9d6a-ee28-4330-9fe5-2dad0045c2ea' User entered '10 Aug 2020 15:32'	System	10 Aug 2020 19:32:23
	System	10 Aug 2020 19:32:23

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 5'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:03:07', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd0e3b205-e388-44e4-8f47-f15dd3c0c222'	System	11 Aug 2020 16:04:08
User entered 'None (1)'	System	11 Aug 2020 16:04:08

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:03:14', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd0e3b205-e388-44e4-8f47-f15dd3c0c222'	System	11 Aug 2020 16:04:08
User entered 'No (N)'	System	11 Aug 2020 16:04:08

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:03:52', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd0e3b205-e388-44e4-8f47-f15dd3c0c222'	System	11 Aug 2020 16:04:08
User entered 'No (N)'	System	11 Aug 2020 16:04:08

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:03:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd0e3b205-e388-44e4-8f47-f15dd3c0c222'	System	11 Aug 2020 16:04:08
User entered 'None (1)'	System	11 Aug 2020 16:04:08

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:04:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd0e3b205-e388-44e4-8f47-f15dd3c0c222'	System	11 Aug 2020 16:04:08
User entered '11 Aug 2020 12:04'	System	11 Aug 2020 16:04:08

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 6'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:06', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a1851e59-1194-476a-b63b-5236ef6731c9' User entered 'None (1)'	System	13 Aug 2020 15:21:24
	System	13 Aug 2020 15:21:24

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:10', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a1851e59-1194-476a-b63b-5236ef6731c9'	System	13 Aug 2020 15:21:24
User entered 'No (N)'	System	13 Aug 2020 15:21:24

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:13', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a1851e59-1194-476a-b63b-5236ef6731c9' User entered 'No (N)'	System	13 Aug 2020 15:21:24
	System	13 Aug 2020 15:21:24

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:18', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a1851e59-1194-476a-b63b-5236ef6731c9' User entered 'None (1)'	System	13 Aug 2020 15:21:24
	System	13 Aug 2020 15:21:24

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:23', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a1851e59-1194-476a-b63b-5236ef6731c9' User entered '13 Aug 2020 11:21'	System	13 Aug 2020 15:21:24
	System	13 Aug 2020 15:21:24

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 7'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e4bc95ac-d5c3-45d9-bacb-59b436496c9d' User entered 'None (1)'	System	13 Aug 2020 16:01:30
	System	13 Aug 2020 16:01:30

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e4bc95ac-d5c3-45d9-bacb-59b436496c9d' User entered 'No (N)'	System	13 Aug 2020 16:01:30
	System	13 Aug 2020 16:01:30

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e4bc95ac-d5c3-45d9-bacb-59b436496c9d' User entered 'No (N)'	System	13 Aug 2020 16:01:30
	System	13 Aug 2020 16:01:30

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:25', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e4bc95ac-d5c3-45d9-bacb-59b436496c9d' User entered 'None (1)'	System	13 Aug 2020 16:01:30
	System	13 Aug 2020 16:01:30

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:28', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e4bc95ac-d5c3-45d9-bacb-59b436496c9d' User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:01:30
	System	13 Aug 2020 16:01:30

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'None (0)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'None (0)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:52', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'None (0)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'None (0)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:34:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'None (0)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:35:01', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'None (0)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:35:12', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered 'No (N)'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-07T15:35:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '787ec91b-9ba3-46d7-b1e2-9580fb3b39a9' User entered '07 Aug 2020 15:35'	System	07 Aug 2020 19:35:18
	System	07 Aug 2020 19:35:18

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 15:20'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 17:50'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'None (0)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:24', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'None (0)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:27', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'None (0)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:31', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'None (0)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'None (0)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:40', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'None (0)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:28:53', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered 'No (N)'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T10:29:06', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9417649f-8d69-49f5-ae12-2fa83fe05ba4' User entered '08 Aug 2020 10:29'	System	08 Aug 2020 14:29:08
	System	08 Aug 2020 14:29:08

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Aug 2020 18:45'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 2'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:11', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'None (0)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:14', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'None (0)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:16', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'None (0)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:18', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'None (0)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'None (0)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'None (0)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:26', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered 'No (N)'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-08T12:04:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'aa66afc7-b172-47ee-8186-dc609d12d96b' User entered '08 Aug 2020 12:04'	System	08 Aug 2020 16:04:37
	System	08 Aug 2020 16:04:37

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 3'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:30', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'None (0)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:33', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'None (0)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:36', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'None (0)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:39', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'None (0)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:41', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'None (0)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'None (0)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered 'No (N)'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-09T12:07:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '876a949e-490b-4816-bdaf-3ee1517e68b5' User entered '09 Aug 2020 12:07'	System	09 Aug 2020 16:07:54
	System	09 Aug 2020 16:07:54

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 4'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:25', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered 'None (0)'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:27', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered 'None (0)'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:30', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered 'None (0)'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered 'None (0)'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered 'None (0)'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:38', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered 'None (0)'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada'	System	10 Aug 2020 19:32:58
User entered 'No (N)'	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-10T15:32:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '12e60bf7-503f-4eb5-a2b0-a84aa13d8ada' User entered '10 Aug 2020 15:32'	System	10 Aug 2020 19:32:58
	System	10 Aug 2020 19:32:58

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 5'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:04:30', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'None (0)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:05:11', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'None (0)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:04:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'None (0)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:04:45', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'None (0)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:04:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'None (0)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:04:52', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'None (0)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:05:06', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered 'No (N)'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-11T12:05:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '56f41f07-4e98-4730-9a91-617a9d002061' User entered '11 Aug 2020 12:05'	System	11 Aug 2020 16:05:33
	System	11 Aug 2020 16:05:33

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 6'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305' User entered 'None (0)'	System	13 Aug 2020 15:21:55
	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305' User entered 'None (0)'	System	13 Aug 2020 15:21:55
	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305' User entered 'None (0)'	System	13 Aug 2020 15:21:55
	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305' User entered 'None (0)'	System	13 Aug 2020 15:21:55
	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:39', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305' User entered 'None (0)'	System	13 Aug 2020 15:21:55
	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305' User entered 'None (0)'	System	13 Aug 2020 15:21:55
	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305'	System	13 Aug 2020 15:21:55
User entered 'No (N)'	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T11:21:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'da4dba5e-da0f-41b7-a399-bcc3053cd305'	System	13 Aug 2020 15:21:55
User entered '13 Aug 2020 11:21'	System	13 Aug 2020 15:21:55

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 7'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190'	System	13 Aug 2020 16:01:52
User entered 'None (0)'	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190'	System	13 Aug 2020 16:01:52
User entered 'None (0)'	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:36', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190'	System	13 Aug 2020 16:01:52
User entered 'None (0)'	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:38', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190' User entered 'None (0)'	System	13 Aug 2020 16:01:52
	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:40', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190' User entered 'None (0)'	System	13 Aug 2020 16:01:52
	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190'	System	13 Aug 2020 16:01:52
User entered 'None (0)'	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190'	System	13 Aug 2020 16:01:52
User entered 'No (N)'	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-08-13T12:01:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e7297878-37f2-4217-be5a-4c258f63f190' User entered '13 Aug 2020 12:01'	System	13 Aug 2020 16:01:52
	System	13 Aug 2020 16:01:52

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 19:07:32

US3222032

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Aug 2020 20:27:22

US3222032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '14 Aug 2020'	(b) (4) Amber Vasquez (b) (4) (b) (4)	14 Aug 2020 20:27:22

US3222032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	Amber Vasquez (b) (4)	14 Aug 2020 20:27:22

US3222032

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	14 Aug 2020 20:27:22

US3222032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	14 Aug 2020 20:27:26

US3222032

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	14 Aug 2020 20:27:26

US3222032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:22

US3222032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User closed query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	06 Sep 2020 14:31:26
answered by data change (Site from System).		
Query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.'	System	06 Sep 2020 14:31:26
User entered '21 Aug 2020' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Sep 2020 14:31:26
User opened query 'Safety Call Day 15 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '4 Sep 2020'	System	04 Sep 2020 19:50:22
	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:22
	(b) (4)	

US3222032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:22

US3222032

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:22

US3222032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:27

US3222032

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	04 Sep 2020 19:50:27

US3222032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:37

US3222032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
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)	
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.' answered by data change (Site from System).	System	06 Sep 2020 14:32:41
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	06 Sep 2020 14:32:41
User entered '28 Aug 2020' reason for change: Data Entry Error	Amber Vasquez (b) (4)	06 Sep 2020 14:32:41
User opened query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '28 Oct 2020' reason for change: Data Entry Error	System	04 Sep 2020 19:51:28
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).	Jennifer Dittman (b) (4)	04 Sep 2020 19:51:28
User entered '4 Sep 2020'	(b) (4)	
	System	04 Sep 2020 19:50:37
	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:37
	(b) (4)	

US3222032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:37

US3222032

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:37

US3222032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:50:43

US3222032

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	04 Sep 2020 19:50:43

US3222032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:51:53

US3222032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	Jennifer Dittman (b) (4)	04 Sep 2020 19:51:53

US3222032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Clinic (Clinic)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:51:53

US3222032

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'VISIT2'	System	04 Sep 2020 19:51:53

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58
	(b) (4)	

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '14:25'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '4 Sep 2020 14:25'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '37.1' C	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Oral (Oral)'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '66'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'bpm'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '16'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'breaths/min'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '128'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '79'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '15:38'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '4 Sep 2020 15:38'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '37.0' C	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Oral (Oral)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '68'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'bpm'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '16'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'breaths/min'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '122'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '79'	Amber Vasquez (b) (4)	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'mmHg'	System	05 Sep 2020 13:40:58

US3222032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Amber Vasquez (b) (4)	05 Sep 2020 13:41:10

US3222032

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	Amber Vasquez (b) (4)	05 Sep 2020 13:41:10

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

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)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Jennifer Dittman (b) (4)	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	Jennifer Dittman (b) (4)	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '15:07'	Jennifer Dittman (b) (4)	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '4 Sep 2020 15:07'	System	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Left Arm (LEFT ARM)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'ONCE'	System	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:04:31

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 19:52:59

US3222032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:41:28

US3222032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:41:28

US3222032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '15:00'	Amber Vasquez (b) (4)	05 Sep 2020 13:41:28

US3222032

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '4 Sep 2020 15:00'	System	05 Sep 2020 13:41:28

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '4 Sep 2020'	Amber Vasquez (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Amber Vasquez (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '15:04'	(b) (4) Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:04:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '4 Sep 2020 15:04'	System	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Vasquez (b) (4) (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Amber Vasquez (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Amber Vasquez (b) (4)	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:04:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered empty.	System	05 Sep 2020 13:41:40

US3222032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Jennifer Dittman (b) (4)	04 Sep 2020 19:53:08

US3222032

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'I'	System	04 Sep 2020 19:53:08

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:55:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71bdae41-77b0-4bbf-9788-a438a3fb5e89' User entered 'Yes (Y)'	System	04 Sep 2020 19:56:18
	System	04 Sep 2020 19:56:18

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:55:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71bdae41-77b0-4bbf-9788-a438a3fb5e89' User entered '98.9'	System	04 Sep 2020 19:56:18
	System	04 Sep 2020 19:56:18

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:01', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71bdae41-77b0-4bbf-9788-a438a3fb5e89' User entered 'No (N)'	System	04 Sep 2020 19:56:18
	System	04 Sep 2020 19:56:18

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71bdae41-77b0-4bbf-9788-a438a3fb5e89' User entered '04 Sep 2020 15:56'	System	04 Sep 2020 19:56:18
	System	04 Sep 2020 19:56:18

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 15:27'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 17:57'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:12:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e113f8e5-540b-4429-834b-6ad1b0006f70' User entered 'Yes (Y)'	System	05 Sep 2020 14:13:21
	System	05 Sep 2020 14:13:21

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:12:54', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e113f8e5-540b-4429-834b-6ad1b0006f70' User entered '100.3'	System	05 Sep 2020 14:13:21
	System	05 Sep 2020 14:13:21

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e113f8e5-540b-4429-834b-6ad1b0006f70'	System	05 Sep 2020 14:13:21
User entered 'No (N)'	System	05 Sep 2020 14:13:21

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e113f8e5-540b-4429-834b-6ad1b0006f70' User entered '05 Sep 2020 10:13'	System	05 Sep 2020 14:13:21
	System	05 Sep 2020 14:13:21

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 18:52'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 2'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:23', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '440718a1-b5c5-4f9e-b195-1b6d011967c1' User entered 'Yes (Y)'	System	06 Sep 2020 13:58:47
	System	06 Sep 2020 13:58:47

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '440718a1-b5c5-4f9e-b195-1b6d011967c1' User entered '98.8'	System	06 Sep 2020 13:58:47
	System	06 Sep 2020 13:58:47

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '440718a1-b5c5-4f9e-b195-1b6d011967c1' User entered 'No (N)'	System	06 Sep 2020 13:58:47
	System	06 Sep 2020 13:58:47

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '440718a1-b5c5-4f9e-b195-1b6d011967c1' User entered '06 Sep 2020 09:58'	System	06 Sep 2020 13:58:47
	System	06 Sep 2020 13:58:47

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 3'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:38:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f2ea9586-69bd-409c-92ae-3ae14c3a6c14' User entered 'Yes (Y)'	System	06 Sep 2020 18:39:43
	System	06 Sep 2020 18:39:43

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:28', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f2ea9586-69bd-409c-92ae-3ae14c3a6c14' User entered '99.4'	System	06 Sep 2020 18:39:43
	System	06 Sep 2020 18:39:43

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f2ea9586-69bd-409c-92ae-3ae14c3a6c14' User entered 'No (N)'	System	06 Sep 2020 18:39:43
	System	06 Sep 2020 18:39:43

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f2ea9586-69bd-409c-92ae-3ae14c3a6c14' User entered '06 Sep 2020 14:39'	System	06 Sep 2020 18:39:43
	System	06 Sep 2020 18:39:43

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 4'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:45:26', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b0c6699e-4627-4cc8-bb7f-1cb806b9e549'	System	07 Sep 2020 16:48:09
User entered 'Yes (Y)'	System	07 Sep 2020 16:48:09

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:47:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b0c6699e-4627-4cc8-bb7f-1cb806b9e549' User entered '99.0'	System	07 Sep 2020 16:48:09
	System	07 Sep 2020 16:48:09

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:47:59', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b0c6699e-4627-4cc8-bb7f-1cb806b9e549'	System	07 Sep 2020 16:48:09
User entered 'No (N)'	System	07 Sep 2020 16:48:09

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:06', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b0c6699e-4627-4cc8-bb7f-1cb806b9e549' User entered '07 Sep 2020 12:48'	System	07 Sep 2020 16:48:09
	System	07 Sep 2020 16:48:09

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 5'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:57:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1de8fe1b-912a-4de1-97b2-0c5d36b5fc31' User entered 'Yes (Y)'	System	09 Sep 2020 13:57:58
	System	09 Sep 2020 13:57:58

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:57:45', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1de8fe1b-912a-4de1-97b2-0c5d36b5fc31' User entered '99.1'	System	09 Sep 2020 13:57:58
	System	09 Sep 2020 13:57:58

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:57:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1de8fe1b-912a-4de1-97b2-0c5d36b5fc31' User entered 'No (N)'	System	09 Sep 2020 13:57:58
	System	09 Sep 2020 13:57:58

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:57:54', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '1de8fe1b-912a-4de1-97b2-0c5d36b5fc31' User entered '09 Sep 2020 09:57'	System	09 Sep 2020 13:57:58
	System	09 Sep 2020 13:57:58

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 6'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:16', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '684e3f1f-0458-4a14-b284-946246412e4b' User entered 'Yes (Y)'	System	09 Sep 2020 16:03:54
	System	09 Sep 2020 16:03:54

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE in °F**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '684e3f1f-0458-4a14-b284-946246412e4b' User entered '99.1'	System	09 Sep 2020 16:03:54
	System	09 Sep 2020 16:03:54

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:23', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '684e3f1f-0458-4a14-b284-946246412e4b' User entered 'No (N)'	System	09 Sep 2020 16:03:54
	System	09 Sep 2020 16:03:54

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:27', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '684e3f1f-0458-4a14-b284-946246412e4b' User entered '09 Sep 2020 12:02'	System	09 Sep 2020 16:03:54
	System	09 Sep 2020 16:03:54

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 7'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:25:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a64aa91a-0c2e-4440-b0c5-aa16d3d56a60' User entered 'Yes (Y)'	System	10 Sep 2020 21:26:05
	System	10 Sep 2020 21:26:05

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:25:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a64aa91a-0c2e-4440-b0c5-aa16d3d56a60' User entered '98.1'	System	10 Sep 2020 21:26:05
	System	10 Sep 2020 21:26:05

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:25:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a64aa91a-0c2e-4440-b0c5-aa16d3d56a60'	System	10 Sep 2020 21:26:05
User entered 'No (N)'	System	10 Sep 2020 21:26:05

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:03', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a64aa91a-0c2e-4440-b0c5-aa16d3d56a60'	System	10 Sep 2020 21:26:05
User entered '10 Sep 2020 17:26'	System	10 Sep 2020 21:26:05

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:25', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e1dc9d1b-0c89-4dc1-b77c-ca3672e68591' User entered 'None (1)'	System	04 Sep 2020 19:56:46
	System	04 Sep 2020 19:56:46

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e1dc9d1b-0c89-4dc1-b77c-ca3672e68591' User entered 'No (N)'	System	04 Sep 2020 19:56:46
	System	04 Sep 2020 19:56:46

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e1dc9d1b-0c89-4dc1-b77c-ca3672e68591' User entered 'No (N)'	System	04 Sep 2020 19:56:46
	System	04 Sep 2020 19:56:46

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:36', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e1dc9d1b-0c89-4dc1-b77c-ca3672e68591' User entered 'None (1)'	System	04 Sep 2020 19:56:46
	System	04 Sep 2020 19:56:46

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e1dc9d1b-0c89-4dc1-b77c-ca3672e68591' User entered '04 Sep 2020 15:56'	System	04 Sep 2020 19:56:46
	System	04 Sep 2020 19:56:46

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 15:27'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 17:57'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:25', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9a218b4c-59d2-4cd2-84b7-49ff512c0dbd' User entered 'None (1)'	System	05 Sep 2020 14:13:43
	System	05 Sep 2020 14:13:43

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9a218b4c-59d2-4cd2-84b7-49ff512c0dbd' User entered 'No (N)'	System	05 Sep 2020 14:13:43
	System	05 Sep 2020 14:13:43

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:31', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9a218b4c-59d2-4cd2-84b7-49ff512c0dbd' User entered 'No (N)'	System	05 Sep 2020 14:13:43
	System	05 Sep 2020 14:13:43

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9a218b4c-59d2-4cd2-84b7-49ff512c0dbd' User entered 'None (1)'	System	05 Sep 2020 14:13:43
	System	05 Sep 2020 14:13:43

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:41', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '9a218b4c-59d2-4cd2-84b7-49ff512c0dbd' User entered '05 Sep 2020 10:13'	System	05 Sep 2020 14:13:43
	System	05 Sep 2020 14:13:43

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 18:52'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 2'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7e7d6fa5-8b08-410a-abe2-908aad975278' User entered 'None (1)'	System	06 Sep 2020 13:59:14
	System	06 Sep 2020 13:59:14

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:52', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7e7d6fa5-8b08-410a-abe2-908aad975278' User entered 'No (N)'	System	06 Sep 2020 13:59:14
	System	06 Sep 2020 13:59:14

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7e7d6fa5-8b08-410a-abe2-908aad975278' User entered 'No (N)'	System	06 Sep 2020 13:59:14
	System	06 Sep 2020 13:59:14

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:58:59', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7e7d6fa5-8b08-410a-abe2-908aad975278' User entered 'None (1)'	System	06 Sep 2020 13:59:14
	System	06 Sep 2020 13:59:14

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7e7d6fa5-8b08-410a-abe2-908aad975278' User entered '06 Sep 2020 09:59'	System	06 Sep 2020 13:59:14
	System	06 Sep 2020 13:59:14

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 3'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'bfcca94a-c7d4-4fc3-811f-aca1d2223476' User entered 'None (1)'	System	06 Sep 2020 18:40:06
	System	06 Sep 2020 18:40:06

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:53', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'bfcca94a-c7d4-4fc3-811f-aca1d2223476' User entered 'No (N)'	System	06 Sep 2020 18:40:06
	System	06 Sep 2020 18:40:06

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'bfcca94a-c7d4-4fc3-811f-aca1d2223476' User entered 'No (N)'	System	06 Sep 2020 18:40:06
	System	06 Sep 2020 18:40:06

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:39:59', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'bfcca94a-c7d4-4fc3-811f-aca1d2223476' User entered 'None (1)'	System	06 Sep 2020 18:40:06
	System	06 Sep 2020 18:40:06

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:02', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'bfcca94a-c7d4-4fc3-811f-aca1d2223476' User entered '06 Sep 2020 14:40'	System	06 Sep 2020 18:40:06
	System	06 Sep 2020 18:40:06

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 4'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:15', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0f33b153-aed4-4589-883d-7c44072bf3e0'	System	07 Sep 2020 16:48:33
User entered 'None (1)'	System	07 Sep 2020 16:48:33

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:18', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0f33b153-aed4-4589-883d-7c44072bf3e0'	System	07 Sep 2020 16:48:33
User entered 'No (N)'	System	07 Sep 2020 16:48:33

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:21', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0f33b153-aed4-4589-883d-7c44072bf3e0'	System	07 Sep 2020 16:48:33
User entered 'No (N)'	System	07 Sep 2020 16:48:33

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:24', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0f33b153-aed4-4589-883d-7c44072bf3e0'	System	07 Sep 2020 16:48:33
User entered 'None (1)'	System	07 Sep 2020 16:48:33

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0f33b153-aed4-4589-883d-7c44072bf3e0' User entered '07 Sep 2020 12:48'	System	07 Sep 2020 16:48:33
	System	07 Sep 2020 16:48:33

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 5'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:57:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3414a3f8-ac31-41a4-b66c-acaaea0211d7'	System	09 Sep 2020 13:58:12
User entered 'None (1)'	System	09 Sep 2020 13:58:12

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:01', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3414a3f8-ac31-41a4-b66c-acaaea0211d7' User entered 'No (N)'	System	09 Sep 2020 13:58:12
	System	09 Sep 2020 13:58:12

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:03', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3414a3f8-ac31-41a4-b66c-acaaea0211d7' User entered 'No (N)'	System	09 Sep 2020 13:58:12
	System	09 Sep 2020 13:58:12

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:06', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3414a3f8-ac31-41a4-b66c-acaaea0211d7'	System	09 Sep 2020 13:58:12
User entered 'None (1)'	System	09 Sep 2020 13:58:12

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3414a3f8-ac31-41a4-b66c-acaaea0211d7' User entered '09 Sep 2020 09:58'	System	09 Sep 2020 13:58:12
	System	09 Sep 2020 13:58:12

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 6'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:31', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f17704ad-90bf-4092-874a-000e9e9abb3a' User entered 'None (1)'	System	09 Sep 2020 16:04:08
	System	09 Sep 2020 16:04:08

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:33', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f17704ad-90bf-4092-874a-000e9e9abb3a' User entered 'No (N)'	System	09 Sep 2020 16:04:08
	System	09 Sep 2020 16:04:08

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:36', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f17704ad-90bf-4092-874a-000e9e9abb3a' User entered 'No (N)'	System	09 Sep 2020 16:04:08
	System	09 Sep 2020 16:04:08

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:39', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f17704ad-90bf-4092-874a-000e9e9abb3a' User entered 'None (1)'	System	09 Sep 2020 16:04:08
	System	09 Sep 2020 16:04:08

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f17704ad-90bf-4092-874a-000e9e9abb3a' User entered '09 Sep 2020 12:02'	System	09 Sep 2020 16:04:08
	System	09 Sep 2020 16:04:08

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 7'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '04887a2f-55af-459f-ba1d-51f8307501f6' User entered 'None (1)'	System	10 Sep 2020 21:26:38
	System	10 Sep 2020 21:26:38

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '04887a2f-55af-459f-ba1d-51f8307501f6' User entered 'No (N)'	System	10 Sep 2020 21:26:38
	System	10 Sep 2020 21:26:38

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '04887a2f-55af-459f-ba1d-51f8307501f6' User entered 'No (N)'	System	10 Sep 2020 21:26:38
	System	10 Sep 2020 21:26:38

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:26', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '04887a2f-55af-459f-ba1d-51f8307501f6' User entered 'None (1)'	System	10 Sep 2020 21:26:38
	System	10 Sep 2020 21:26:38

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:36', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '04887a2f-55af-459f-ba1d-51f8307501f6' User entered '10 Sep 2020 17:26'	System	10 Sep 2020 21:26:38
	System	10 Sep 2020 21:26:38

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'None (0)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:56:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'None (0)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:57:02', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'None (0)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:57:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'None (0)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:57:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'None (0)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:57:11', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'None (0)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:57:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered 'No (N)'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-04T15:57:24', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '36cbb036-f4f4-491a-9d9e-6f3fbfacd50f' User entered '04 Sep 2020 15:57'	System	04 Sep 2020 19:57:28
	System	04 Sep 2020 19:57:28

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 15:27'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 17:57'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:54', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'None (0)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:13:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'None (0)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:14:02', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'None (0)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:14:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'None (0)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:14:11', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'None (0)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:14:15', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'None (0)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:14:40', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered 'No (N)'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-05T10:14:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'd4828ed9-1a21-48cf-b89d-cbf4b2685b8b' User entered '05 Sep 2020 10:14'	System	05 Sep 2020 14:14:52
	System	05 Sep 2020 14:14:52

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '04 Sep 2020 18:52'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 2'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:10', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered 'None (0)'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:12', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered 'None (0)'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:15', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered 'None (0)'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:18', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered 'None (0)'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:21', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered 'None (0)'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:23', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered 'None (0)'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:26', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5'	System	06 Sep 2020 13:59:42
User entered 'No (N)'	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T09:59:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71337807-2608-4511-9b49-106c53beccd5' User entered '06 Sep 2020 09:59'	System	06 Sep 2020 13:59:42
	System	06 Sep 2020 13:59:42

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 3'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'None (0)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:11', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'None (0)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:13', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'None (0)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'None (0)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'None (0)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'None (0)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:40', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered 'Yes (Y)'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-06T14:40:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '7fcd5c1b-9c31-44ed-a17b-fbc2c96d963a' User entered '06 Sep 2020 14:40'	System	06 Sep 2020 18:40:49
	System	06 Sep 2020 18:40:49

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 4'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'None (0)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:38', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'None (0)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:40', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'None (0)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'None (0)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:45', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'None (0)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'None (0)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered 'No (N)'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-07T12:48:54', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '64fde667-a99d-408e-90f4-aaf32db8378f' User entered '07 Sep 2020 12:48'	System	07 Sep 2020 16:48:59
	System	07 Sep 2020 16:48:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 5'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:13', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'None (0)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:15', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'None (0)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:17', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'None (0)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:20', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'None (0)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'None (0)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:24', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'None (0)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:28', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered 'No (N)'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T09:58:32', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e8c848c2-92d9-44cd-ab92-b01bae893486' User entered '09 Sep 2020 09:58'	System	09 Sep 2020 13:58:34
	System	09 Sep 2020 13:58:34

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 6'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered 'None (0)'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered 'None (0)'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered 'None (0)'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered 'None (0)'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:53', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered 'None (0)'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered 'None (0)'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:02:57', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23'	System	09 Sep 2020 16:04:23
User entered 'No (N)'	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-09T12:03:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '676003f5-57ac-47c7-ac51-aef6ce579e23' User entered '09 Sep 2020 12:03'	System	09 Sep 2020 16:04:23
	System	09 Sep 2020 16:04:23

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	04 Sep 2020 19:52:59
User entered 'Day 7'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:42', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered 'None (0)'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered 'None (0)'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered 'None (0)'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered 'None (0)'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered 'None (0)'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:53', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered 'None (0)'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7'	System	10 Sep 2020 21:27:01
User entered 'No (N)'	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-09-10T17:26:59', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b5bdbbe00-dd12-4725-bb4d-179cd6a071d7' User entered '10 Sep 2020 17:26'	System	10 Sep 2020 21:27:01
	System	10 Sep 2020 21:27:01

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 19:52:59

US3222032

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:04:31

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 19:52:59

US3222032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:35:44

US3222032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '11 Sep 2020'	Albert Garcia (b) (4)	07 Oct 2020 11:35:44

US3222032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Oct 2020 11:35:44

US3222032

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 11:35:44

US3222032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:35:59

US3222032

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	07 Oct 2020 11:35:59

US3222032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:36:18

US3222032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '18 Sep 2020'	Albert Garcia (b) (4)	07 Oct 2020 11:36:18

US3222032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Oct 2020 11:36:18

US3222032

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:36:18

US3222032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:36:27

US3222032

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	07 Oct 2020 11:36:27

US3222032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:36:47

US3222032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '25 Sep 2020'	Albert Garcia (b) (4)	07 Oct 2020 11:36:47

US3222032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	Albert Garcia (b) (4)	07 Oct 2020 11:36:47

US3222032

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:36:47

US3222032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:36:58

US3222032

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	07 Oct 2020 11:36:58

US3222032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:37:11

US3222032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '6 Oct 2020'	Albert Garcia (b) (4)	07 Oct 2020 11:37:11

US3222032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Clinic (Clinic)'	Albert Garcia (b) (4)	07 Oct 2020 11:37:11

US3222032

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'VISIT3'	System	07 Oct 2020 11:37:11

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered empty.	System	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered empty.	System	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered empty.	System	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered empty.	System	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered empty.	System	07 Oct 2020 11:37:16

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34

US3222032

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34

US3222032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	07 Oct 2020 11:37:20

US3222032

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	Albert Garcia (b) (4)	07 Oct 2020 11:37:20

US3222032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:37:30

US3222032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '6 Oct 2020'	Albert Garcia (b) (4)	07 Oct 2020 11:37:30

US3222032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '12:40'	Albert Garcia (b) (4)	07 Oct 2020 11:37:30

US3222032

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered '6 Oct 2020 12:40'	System	07 Oct 2020 11:37:30

US3222032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	Albert Garcia (b) (4)	07 Oct 2020 11:37:33

US3222032

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:34
User entered 'I'	System	07 Oct 2020 11:37:33

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 64'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-07T11:12:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c25fb571-d6b9-44f3-8975-772dd02c4744'	System	07 Oct 2020 15:13:27
User entered 'No (N)'	System	07 Oct 2020 15:13:27

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-07T11:12:29', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c25fb571-d6b9-44f3-8975-772dd02c4744'	System	07 Oct 2020 15:13:27
User entered 'No (N)'	System	07 Oct 2020 15:13:27

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-07T11:13:25', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c25fb571-d6b9-44f3-8975-772dd02c4744' User entered '07 Oct 2020 11:13:25'	System	07 Oct 2020 15:13:27
	System	07 Oct 2020 15:13:27

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 71'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-14T08:49:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '2810cb92-288e-45b2-a0bf-c6873f639f1b' User entered 'No (N)'	System	14 Oct 2020 12:50:18
	System	14 Oct 2020 12:50:18

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-14T08:50:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '2810cb92-288e-45b2-a0bf-c6873f639f1b' User entered 'No (N)'	System	14 Oct 2020 12:50:18
	System	14 Oct 2020 12:50:18

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-14T08:50:16', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '2810cb92-288e-45b2-a0bf-c6873f639f1b' User entered '14 Oct 2020 08:50:16'	System	14 Oct 2020 12:50:18
	System	14 Oct 2020 12:50:18

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 78'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-24T17:59:40', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b34fd6de-c88f-491b-bf30-8f18457ee216'	System	24 Oct 2020 21:59:51
User entered 'No (N)'	System	24 Oct 2020 21:59:51

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-24T17:59:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b34fd6de-c88f-491b-bf30-8f18457ee216'	System	24 Oct 2020 21:59:51
User entered 'No (N)'	System	24 Oct 2020 21:59:51

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-10-24T17:59:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'b34fd6de-c88f-491b-bf30-8f18457ee216' User entered '24 Oct 2020 17:59:50'	System	24 Oct 2020 21:59:51
	System	24 Oct 2020 21:59:51

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 92'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-06T12:00:52', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '4891ea25-aa6a-4511-ba29-ec91bc0aac96'	System	11 Nov 2020 05:50:45
User entered 'No (N)'	System	11 Nov 2020 05:50:45

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-06T12:01:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '4891ea25-aa6a-4511-ba29-ec91bc0aac96'	System	11 Nov 2020 05:50:45
User entered 'No (N)'	System	11 Nov 2020 05:50:45

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-06T12:01:07', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '4891ea25-aa6a-4511-ba29-ec91bc0aac96' User entered '06 Nov 2020 12:01:07'	System	11 Nov 2020 05:50:45
	System	11 Nov 2020 05:50:45

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 99'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-11T00:50:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0aa06b56-cccc-4898-90a3-e247fd86b1de' User entered 'No (N)'	System	11 Nov 2020 05:51:02
	System	11 Nov 2020 05:51:02

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-11T00:50:49', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0aa06b56-cccc-4898-90a3-e247fd86b1de' User entered 'No (N)'	System	11 Nov 2020 05:51:02
	System	11 Nov 2020 05:51:02

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-11T00:50:54', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '0aa06b56-cccc-4898-90a3-e247fd86b1de' User entered '11 Nov 2020 00:50:54'	System	11 Nov 2020 05:51:02
	System	11 Nov 2020 05:51:02

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:50:28
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46
Data entry locked.	System	07 Aug 2020 19:07:32
User entered 'Day 106'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Please 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)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Please 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)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Please 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)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 19:07:32

US3222032

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 15:59:46
Data entry locked.	System	07 Aug 2020 19:07:32
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 19:07:32

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-22T08:10:54', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '938c510a-7895-4425-a4c9-a4a9b263e465' User entered 'No (N)'	System	22 Nov 2020 13:11:10
	System	22 Nov 2020 13:11:10

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-22T08:11:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '938c510a-7895-4425-a4c9-a4a9b263e465'	System	22 Nov 2020 13:11:10
User entered 'No (N)'	System	22 Nov 2020 13:11:10

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-22T08:11:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '938c510a-7895-4425-a4c9-a4a9b263e465' User entered '22 Nov 2020 08:11:08'	System	22 Nov 2020 13:11:10
	System	22 Nov 2020 13:11:10

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-30T11:59:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '694528f6-6f9b-4f8c-a7fd-1e1c8d251894'	System	30 Nov 2020 18:00:08
User entered 'No (N)'	System	30 Nov 2020 18:00:08

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-30T11:59:58', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '694528f6-6f9b-4f8c-a7fd-1e1c8d251894'	System	30 Nov 2020 18:00:08
User entered 'No (N)'	System	30 Nov 2020 18:00:08

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-11-30T12:00:03', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '694528f6-6f9b-4f8c-a7fd-1e1c8d251894' User entered '30 Nov 2020 12:00:03'	System	30 Nov 2020 18:00:08
	System	30 Nov 2020 18:00:08

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-06T07:58:57', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f5f6257f-9ea1-4d5c-adc6-1da9885360ec' User entered 'No (N)'	System	06 Dec 2020 12:59:12
	System	06 Dec 2020 12:59:12

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-06T07:59:03', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f5f6257f-9ea1-4d5c-adc6-1da9885360ec' User entered 'No (N)'	System	06 Dec 2020 12:59:12

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-06T07:59:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f5f6257f-9ea1-4d5c-adc6-1da9885360ec' User entered '06 Dec 2020 07:59:08'	System	06 Dec 2020 12:59:12
	System	06 Dec 2020 12:59:12

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-13T12:43:06', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '95b0511c-2cd3-401b-8ec1-f883d83dad70' User entered 'Yes (Y)'	System	13 Dec 2020 17:44:24
	System	13 Dec 2020 17:44:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-13T12:43:13', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '95b0511c-2cd3-401b-8ec1-f883d83dad70' User entered 'No (N)'	System	13 Dec 2020 17:44:24
	System	13 Dec 2020 17:44:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-13T12:43:19', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '95b0511c-2cd3-401b-8ec1-f883d83dad70' User entered 'No (N)'	System	13 Dec 2020 17:44:24
	System	13 Dec 2020 17:44:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-13T12:43:48', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '95b0511c-2cd3-401b-8ec1-f883d83dad70' User entered 'Yes (Y)'	System	13 Dec 2020 17:44:24
	System	13 Dec 2020 17:44:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Please 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-13T12:44:01', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '95b0511c-2cd3-401b-8ec1-f883d83dad70'	System	13 Dec 2020 17:44:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	13 Dec 2020 17:44:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-13T12:44:15', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '95b0511c-2cd3-401b-8ec1-f883d83dad70' User entered '13 Dec 2020 12:44:15'	System	13 Dec 2020 17:44:24
	System	13 Dec 2020 17:44:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 08:27:34
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'USA-US104-2020-MRNA-1273-P301000025-patient was hospitalized SAE reported' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:38:21
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 03:50:40
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-20T08:20:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ab7c7f61-6499-4559-876f-463ddffd280c'	System	20 Dec 2020 13:21:18
User entered 'Yes (Y)'	System	20 Dec 2020 13:21:18

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-20T08:20:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ab7c7f61-6499-4559-876f-463ddffd280c'	System	20 Dec 2020 13:21:18
User entered 'No (N)'	System	20 Dec 2020 13:21:18

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-20T08:20:48', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ab7c7f61-6499-4559-876f-463ddffd280c'	System	20 Dec 2020 13:21:18
User entered 'No (N)'	System	20 Dec 2020 13:21:18

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-20T08:20:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ab7c7f61-6499-4559-876f-463ddffd280c' User entered 'Yes (Y)'	System	20 Dec 2020 13:21:18
	System	20 Dec 2020 13:21:18

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Please 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-20T08:21:03', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ab7c7f61-6499-4559-876f-463ddffd280c'	System	20 Dec 2020 13:21:18
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Dec 2020 13:21:18

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-20T08:21:08', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ab7c7f61-6499-4559-876f-463ddffd280c' User entered '20 Dec 2020 08:21:08'	System	20 Dec 2020 13:21:18
	System	20 Dec 2020 13:21:18

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-27T04:09:18', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c5412bdb-f3fb-4710-b0d8-b17deee8c355'	System	27 Dec 2020 09:09:32
User entered 'No (N)'	System	27 Dec 2020 09:09:32

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-27T04:09:22', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c5412bdb-f3fb-4710-b0d8-b17deee8c355'	System	27 Dec 2020 09:09:32
User entered 'No (N)'	System	27 Dec 2020 09:09:32

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2020-12-27T04:09:30', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c5412bdb-f3fb-4710-b0d8-b17deee8c355' User entered '27 Dec 2020 04:09:30'	System	27 Dec 2020 09:09:32
	System	27 Dec 2020 09:09:32

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-03T08:05:31', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '49028df5-fb3f-4b8c-8803-a57b179bab8d' User entered 'No (N)'	System	03 Jan 2021 13:05:43
	System	03 Jan 2021 13:05:43

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-03T08:05:35', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '49028df5-fb3f-4b8c-8803-a57b179bab8d' User entered 'No (N)'	System	03 Jan 2021 13:05:43

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-03T08:05:39', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '49028df5-fb3f-4b8c-8803-a57b179bab8d' User entered '03 Jan 2021 08:05:39'	System	03 Jan 2021 13:05:43
	System	03 Jan 2021 13:05:43

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-10T10:36:45', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '348dfaf6-767b-4559-8b2a-b9eb3174245f' User entered 'No (N)'	System	10 Jan 2021 15:37:02

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-10T10:36:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '348dfaf6-767b-4559-8b2a-b9eb3174245f' User entered 'No (N)'	System	10 Jan 2021 15:37:02

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-10T10:37:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '348dfaf6-767b-4559-8b2a-b9eb3174245f' User entered '10 Jan 2021 10:37:00'	System	10 Jan 2021 15:37:02
	System	10 Jan 2021 15:37:02

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-19T12:00:43', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '034e0481-2b91-433d-82b1-95c2b4805c2d' User entered 'No (N)'	System	27 Jan 2021 19:33:17
	System	27 Jan 2021 19:33:17

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-19T12:00:48', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '034e0481-2b91-433d-82b1-95c2b4805c2d'	System	27 Jan 2021 19:33:17
User entered 'No (N)'	System	27 Jan 2021 19:33:17

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-19T12:00:56', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '034e0481-2b91-433d-82b1-95c2b4805c2d' User entered '19 Jan 2021 12:00:56'	System	27 Jan 2021 19:33:17

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-27T14:33:24', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a630c859-30d3-4e87-91be-9033052574b0'	System	27 Jan 2021 19:33:45
User entered 'No (N)'	System	27 Jan 2021 19:33:45

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-27T14:33:37', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a630c859-30d3-4e87-91be-9033052574b0'	System	27 Jan 2021 19:33:45
User entered 'No (N)'	System	27 Jan 2021 19:33:45

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-27T14:33:44', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'a630c859-30d3-4e87-91be-9033052574b0' User entered '27 Jan 2021 14:33:44'	System	27 Jan 2021 19:33:45

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-31T08:16:47', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ff268147-7801-4e71-bcf2-e8933147049f'	System	31 Jan 2021 13:17:00
User entered 'No (N)'	System	31 Jan 2021 13:17:00

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-31T08:16:51', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ff268147-7801-4e71-bcf2-e8933147049f'	System	31 Jan 2021 13:17:00
User entered 'No (N)'	System	31 Jan 2021 13:17:00

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-01-31T08:16:55', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'ff268147-7801-4e71-bcf2-e8933147049f' User entered '31 Jan 2021 08:16:55'	System	31 Jan 2021 13:17:00
	System	31 Jan 2021 13:17:00

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-07T12:16:26', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'df429621-86ac-47ac-b3f4-8bb65a61dd9f' User entered 'No (N)'	System	07 Feb 2021 18:16:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-07T12:16:05', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'df429621-86ac-47ac-b3f4-8bb65a61dd9f' User entered 'No (N)'	System	07 Feb 2021 18:16:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-07T12:16:41', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'df429621-86ac-47ac-b3f4-8bb65a61dd9f' User entered '07 Feb 2021 12:16:41'	System	07 Feb 2021 18:16:46
	System	07 Feb 2021 18:16:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-14T00:25:45', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '893c91e1-fb44-4718-a6d4-4f05d721f35f' User entered 'No (N)'	System	14 Feb 2021 06:27:28
	System	14 Feb 2021 06:27:28

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-14T00:25:34', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '893c91e1-fb44-4718-a6d4-4f05d721f35f' User entered 'No (N)'	System	14 Feb 2021 06:27:28
	System	14 Feb 2021 06:27:28

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-14T00:27:26', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '893c91e1-fb44-4718-a6d4-4f05d721f35f' User entered '14 Feb 2021 00:27:26'	System	14 Feb 2021 06:27:28
	System	14 Feb 2021 06:27:28

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-21T08:17:41', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c73444a4-aac2-43c0-b8cd-0483ea6910cd' User entered 'No (N)'	System	21 Feb 2021 13:17:52
	System	21 Feb 2021 13:17:52

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-21T08:17:46', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c73444a4-aac2-43c0-b8cd-0483ea6910cd' User entered 'No (N)'	System	21 Feb 2021 13:17:52
	System	21 Feb 2021 13:17:52

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-02-21T08:17:50', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'c73444a4-aac2-43c0-b8cd-0483ea6910cd' User entered '21 Feb 2021 08:17:50'	System	21 Feb 2021 13:17:52
	System	21 Feb 2021 13:17:52

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-01T18:39:15-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'fc3e7d6e-cf3b-4af8-a13c-a26d290d8583'	System	01 Mar 2021 23:40:02
User entered 'No (N)'	System	01 Mar 2021 23:40:02

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-01T18:39:44-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'fc3e7d6e-cf3b-4af8-a13c-a26d290d8583'	System	01 Mar 2021 23:40:02
User entered 'No (N)'	System	01 Mar 2021 23:40:02

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-01T18:39:48-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'fc3e7d6e-cf3b-4af8-a13c-a26d290d8583'	System	01 Mar 2021 23:40:02
User entered '01 Mar 2021 18:39:48'	System	01 Mar 2021 23:40:02

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-07T22:06:38-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'db202dba-de6a-404f-88a3-54a3c445f9da'	System	16 Mar 2021 17:08:20
User entered 'No (N)'	System	16 Mar 2021 17:08:20

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-07T22:06:43-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'db202dba-de6a-404f-88a3-54a3c445f9da'	System	16 Mar 2021 17:08:20
User entered 'No (N)'	System	16 Mar 2021 17:08:20

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-07T22:06:47-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'db202dba-de6a-404f-88a3-54a3c445f9da' User entered '07 Mar 2021 22:06:47'	System	16 Mar 2021 17:08:20
	System	16 Mar 2021 17:08:20

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-16T13:08:01-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6c6b336-61a8-4d2a-8147-bb7a6ac8bbc6'	System	16 Mar 2021 17:08:24
User entered 'No (N)'	System	16 Mar 2021 17:08:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-16T13:08:06-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6c6b336-61a8-4d2a-8147-bb7a6ac8bbc6'	System	16 Mar 2021 17:08:24
User entered 'No (N)'	System	16 Mar 2021 17:08:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-16T13:08:10-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'f6c6b336-61a8-4d2a-8147-bb7a6ac8bbc6' User entered '16 Mar 2021 13:08:10'	System	16 Mar 2021 17:08:24
	System	16 Mar 2021 17:08:24

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-21T00:08:31-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8e0aa472-fc32-4da5-b3ef-0262e340e5ee'	System	21 Mar 2021 04:08:49
User entered 'No (N)'	System	21 Mar 2021 04:08:49

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-21T00:08:38-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8e0aa472-fc32-4da5-b3ef-0262e340e5ee'	System	21 Mar 2021 04:08:49
User entered 'No (N)'	System	21 Mar 2021 04:08:49

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-21T00:08:43-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '8e0aa472-fc32-4da5-b3ef-0262e340e5ee' User entered '21 Mar 2021 00:08:43'	System	21 Mar 2021 04:08:49
	System	21 Mar 2021 04:08:49

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-28T09:40:39-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3818a032-c2ca-42b2-9f2f-1975075a037c'	System	28 Mar 2021 13:40:56
User entered 'No (N)'	System	28 Mar 2021 13:40:56

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-28T09:40:44-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3818a032-c2ca-42b2-9f2f-1975075a037c'	System	28 Mar 2021 13:40:56
User entered 'No (N)'	System	28 Mar 2021 13:40:56

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-28T09:40:51-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3818a032-c2ca-42b2-9f2f-1975075a037c' User entered '28 Mar 2021 09:40:51'	System	28 Mar 2021 13:40:56
	System	28 Mar 2021 13:40:56

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-05T19:29:04-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '49a29380-6560-4c9f-8622-bf72dd650769' User entered 'No (N)'	System	05 Apr 2021 23:29:26
	System	05 Apr 2021 23:29:26

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-05T19:29:20-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '49a29380-6560-4c9f-8622-bf72dd650769' User entered 'No (N)'	System	05 Apr 2021 23:29:26
	System	05 Apr 2021 23:29:26

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-05T19:29:23-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '49a29380-6560-4c9f-8622-bf72dd650769' User entered '05 Apr 2021 19:29:23'	System	05 Apr 2021 23:29:26
	System	05 Apr 2021 23:29:26

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-11T08:10:16-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e3d1e373-dd6e-4d09-a9a3-db0114bfd5bb'	System	11 Apr 2021 12:10:33
User entered 'No (N)'	System	11 Apr 2021 12:10:33

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-11T08:10:25-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e3d1e373-dd6e-4d09-a9a3-db0114bfd5bb'	System	11 Apr 2021 12:10:33
User entered 'No (N)'	System	11 Apr 2021 12:10:33

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-11T08:10:28-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: 'e3d1e373-dd6e-4d09-a9a3-db0114bfd5bb'	System	11 Apr 2021 12:10:33
User entered '11 Apr 2021 08:10:28'	System	11 Apr 2021 12:10:33

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-20T13:06:15-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3621101d-7a32-451b-a4ac-b02ed948265f' User entered 'No (N)'	System	26 Apr 2021 17:04:52
	System	26 Apr 2021 17:04:52

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-20T13:06:19-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3621101d-7a32-451b-a4ac-b02ed948265f' User entered 'No (N)'	System	26 Apr 2021 17:04:52
	System	26 Apr 2021 17:04:52

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-20T13:06:23-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '3621101d-7a32-451b-a4ac-b02ed948265f' User entered '20 Apr 2021 13:06:23'	System	26 Apr 2021 17:04:52
	System	26 Apr 2021 17:04:52

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-26T13:02:18-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '4a6a87b4-dd5d-4c8b-af38-fda087f5198d' User entered 'No (N)'	System	26 Apr 2021 17:04:56
	System	26 Apr 2021 17:04:56

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-26T13:02:19-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '4a6a87b4-dd5d-4c8b-af38-fda087f5198d' User entered 'No (N)'	System	26 Apr 2021 17:04:56
	System	26 Apr 2021 17:04:56

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-04-26T13:02:23-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '4a6a87b4-dd5d-4c8b-af38-fda087f5198d' User entered '26 Apr 2021 13:02:23'	System	26 Apr 2021 17:04:56
	System	26 Apr 2021 17:04:56

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-05-02T23:31:57-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71d5a8a1-b196-44e3-8d09-ab42f2b15ff1'	System	03 May 2021 03:32:09
User entered 'No (N)'	System	03 May 2021 03:32:09

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

Have you been exposed to someone with 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 (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-05-02T23:32:00-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71d5a8a1-b196-44e3-8d09-ab42f2b15ff1'	System	03 May 2021 03:32:09
User entered 'No (N)'	System	03 May 2021 03:32:09

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-05-02T23:32:03-04:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '71d5a8a1-b196-44e3-8d09-ab42f2b15ff1'	System	03 May 2021 03:32:09
User entered '02 May 2021 23:32:03'	System	03 May 2021 03:32:09

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 15:59:46

US3222032

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:04:31

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 15:59:46
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 15:59:46

US3222032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:31

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)	25 Apr 2021 06:15:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-01T18:38:59-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '2d91af1a-1feb-49fb-a296-27fe2bc2b90d'	System	01 Mar 2021 23:39:15
User entered 'No (N)'	System	01 Mar 2021 23:39:15

US3222032

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:04:31

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 06:15:23
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C4C6CB3D-7D16-4D05-826E-215462173DE4)', Time: '2021-03-01T18:39:07-05:00', User OID: 'PatientReportedOutcome (US3222032)', ODM File OID: '2d91af1a-1feb-49fb-a296-27fe2bc2b90d' User entered '01 Mar 2021 18:39:07'	System	01 Mar 2021 23:39:15
	System	01 Mar 2021 23:39:15

US3222032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	18 Nov 2020 14:35:56

US3222032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '29 Oct 2020'	Crystal Paccione (b) (4)	18 Nov 2020 14:35:56

US3222032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	18 Nov 2020 14:35:56

US3222032

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) Crystal Paccione (b) (4)	18 Nov 2020 14:35:56

US3222032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Crystal Paccione (b) (4) (b) (4)	18 Nov 2020 14:36:16

US3222032

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:38:33
User entered 'I'	System	18 Nov 2020 14:36:16

US3222032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:54

US3222032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '01 Dec 2020'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:54

US3222032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:54

US3222032

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:31:54

US3222032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:32:05

US3222032

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User entered 'I'	System	05 Jan 2021 19:32:05

US3222032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:34:11

US3222032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '05 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:34:11

US3222032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:34:11

US3222032

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:34:11

US3222032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 19:34:19

US3222032

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User entered 'I'	System	05 Jan 2021 19:34:19

US3222032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:19:48

US3222032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered '02 Feb 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:19:48

US3222032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:19:48

US3222032

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:19:48

US3222032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:19:58

US3222032

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:26:33
User entered 'I'	System	03 Mar 2021 22:19:58

US3222032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:20:21

US3222032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered '03 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:20:21

US3222032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Clinic (Clinic)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:20:21

US3222032

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered 'VISIT4'	System	03 Mar 2021 22:20:21

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered empty.	System	31 Mar 2021 13:36:19

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54

US3222032

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:04:31

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54

US3222032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:20:34

US3222032

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:04:31

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered empty.	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:20:34

US3222032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:21:01

US3222032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered '03 Mar 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:21:01

US3222032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered '11:35'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:21:01

US3222032

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '03 Mar 2021 11:35'	System	03 Mar 2021 22:21:01

US3222032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User signature succeeded.	Vicki Miller (b) (4)	05 Mar 2021 21:06:17
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	03 Mar 2021 22:21:07

US3222032

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 06:57:54
User entered '1'	System	03 Mar 2021 22:21:07

US3222032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:33:53

US3222032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered '31 Mar 2021'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:33:53

US3222032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:33:53

US3222032

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered empty.	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:33:53

US3222032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	31 Mar 2021 12:34:18

US3222032

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	31 Mar 2021 12:34:18

US3222032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	03 May 2021 15:52:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:13:13

US3222032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	03 May 2021 15:52:57
User entered '30 Apr 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:13:13

US3222032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	03 May 2021 15:52:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:13:13

US3222032

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:04:31

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	03 May 2021 15:52:57
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:13:13

US3222032

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	03 May 2021 15:52:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 14:13:18

US3222032

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:04:31

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 14:13:18

US3222032

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:02:11

US3222032

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '20 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:02:11

US3222032

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[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 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'Clinic (Clinic)'	Diana Toney (b) (4)	20 Jan 2021 19:02:11

US3222032

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

Form: Visit Date

Generated On: 09 Jun 2021 16:04:31

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User entered 'UNBLND_DECIDE'	System	20 Jan 2021 19:02:11

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered '20 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

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 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:11:24
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:22:21

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	25 Mar 2021 17:11:24
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 03:22:21

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered '20 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'No (N)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User entered empty.	System	20 Jan 2021 19:06:28

US3222032

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

Form: Unblinding

Generated On: 09 Jun 2021 16:04:31

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User entered empty.	System	20 Jan 2021 19:06:28

US3222032

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:45

US3222032

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered '20 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:45

US3222032

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered '11:40'	Diana Toney (b) (4)	20 Jan 2021 19:06:45

US3222032

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:04:31

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User entered '20 Jan 2021 11:40'	System	20 Jan 2021 19:06:45

US3222032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:31

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'Yes (Y)'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:59

US3222032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:31

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered '20 Jan 2021'	(b) (4) Diana Toney (b) (4) (b) (4)	20 Jan 2021 19:06:59

US3222032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:31

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered '11:43'	Diana Toney (b) (4)	20 Jan 2021 19:06:59

US3222032

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:04:31

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:18:25
User entered '20 Jan 2021 11:43'	System	20 Jan 2021 19:06:59

US3222032

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:04:31

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:42
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	douglas winter (b) (4)	15 Dec 2020 12:48:42
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 15:04:20
	(b) (4)	

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Dec 2020 20:20:13
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 18:47:30
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 18:46:58
User entered	System	15 Dec 2020 18:46:36
'USA-US104-2020-mRNA-1273-P301000025'		
User entered 'New'	(b) (4), (b) (6)	15 Dec 2020 18:46:36

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per MM: please provide mode details regarding disease aetiology and final diagnosis. ' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 00:05:57
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:19:46
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' answered with 'THERE IS NO KNOWN UNDERLYING CAUSATION FOR THE ELEVATION.' (Site from Safety).	Albert Garcia (b) (4) (b) (4)	22 Dec 2020 13:24:18
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:21:48
User coded data point as SOC: Investigations, HLT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 12:59:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Dec 2020 12:59:00
Data point term sent to Coder	System	15 Dec 2020 12:58:05
User entered 'ELEVATED LIVER ENZYMES'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if start date should be 13 DEC 2020 (per paper SAE form). Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Dec 2020 20:19:49
Query 'PV Query: Please confirm if start date should be 13 DEC 2020 (per paper SAE form). Please update as applicable.' answered with 'UPDATED' (Site from Safety).	Albert Garcia (b) (4)	22 Dec 2020 13:25:33
User entered '13 Dec 2020' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 13:25:12
User opened query 'PV Query: Please confirm if start date should be 13 DEC 2020 (per paper SAE form). Please update as applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:21:06
User entered '14 Dec 2020'	douglas winter (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

Start time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:51:46
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'AE CONTINUES' (Site from Safety).	douglas winter (b) (4)	12 Apr 2021 12:24:48
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:20:39
User entered empty.	douglas winter (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

End time (00:00-23:59)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Severity](#)

Audit	User	Time (GMT)
User entered 'Grade 3/Severe (Grade 3/Severe)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	25 Dec 2020 07:20:12
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date is provided, please review. ' (Site from System).	Albert Garcia (b) (4)	15 Dec 2020 17:24:38
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	15 Dec 2020 12:57:57
User entered 'I'	douglas winter (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User entered '13 Dec 2020'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 00:12:06
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 'SO FAR WE HAVE NOT BEEN SUCCESSFUL OBTAINING MEDICAL RECORDS. I'LL REQUEST ONCE MORE.' (Site from Safety).	douglas winter (b) (4)	20 Apr 2021 19:46:57
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 15:51:53
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'UPDATED' (Site from Safety).	douglas winter (b) (4)	12 Apr 2021 12:25:46
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	12 Apr 2021 12:25:35
User entered '21 Dec 2020' reason for change: Data Entry Error	douglas winter (b) (4)	12 Apr 2021 12:25:35
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	01 Apr 2021 18:29:49
User entered '21 Dec 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 18:29:49
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)	21 Dec 2020 19:26:44
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:21:25
User entered empty.	douglas winter (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'No (N)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User entered 'Not Related (NOT RELATED)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User entered 'Not Applicable (NOT APPLICABLE)'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Apr 2021 19:40:20
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 19:40:20
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Apr 2021 19:40:07
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Response Noted, as per your query response please uncheck the Concomitant Medication check box if Medical records are not available.' (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 08:58:18
Query 'Per CDM: Response Noted, as per your query response please uncheck the Concomitant Medication check box if Medical records are not available.' answered with 'Medical records not available at this point. Will update when medical records obtained and if subject took con meds.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 19:41:15
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Apr 2021 19:40:07
User opened query 'Per CDM: Response Noted, as per your query response please uncheck the Concomitant Medication check box if Medical records are not available.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:17:28
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 14:17:28
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'SO FAR WE HAVE NOT BEEN ABLE TO OBTAIN MEDICAL RECORDS. I WILL REQUEST ONCE MORE.' (Site from DM).	douglas winter (b) (4) (b) (4)	20 Apr 2021 19:50:28
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:36:27
User entered '1'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 00:12:11
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'AS OF 31MARCH, SHE CONTINUES TO HAVE ELEVATED LIVER ENZYMES' (Site from Safety).	douglas winter (b) (4)	20 Apr 2021 19:52:13
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:18:48
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	douglas winter (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User entered empty.	douglas winter (b) (4) (b) (4)	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide hospital records to include any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 00:12:20
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 00:12:17
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Apr 2021 00:12:14
Query 'PV Query: Please provide hospital records to include any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'SO FAR WE HAVE NOT BEEN ABLE TO OBTAIN MEDICAL RECORDS. I WILL REQUEST ONCE MORE.' (Site from Safety).	douglas winter (b) (4)	20 Apr 2021 19:52:29
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'SO FAR WE HAVE NOT BEEN ABLE TO OBTAIN MEDICAL RECORDS. I WILL REQUEST ONCE MORE.' (Site from Safety).	douglas winter (b) (4)	20 Apr 2021 19:52:24
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'SO FAR WE HAVE NOT BEEN ABLE TO OBTAIN MEDICAL RECORDS. I WILL REQUEST ONCE MORE.' (Site from Safety).	douglas winter (b) (4)	20 Apr 2021 19:52:20

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide hospital records to include any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:28:48
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:22:31
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 19:18:27
User entered 'I WAS INFORMED BY THE SAFETY CALL STAFF ON 14/DEC/2020 @ 13:58 THAT THIS SUBJECT WAS HOSPITALIZED FOR AN UNSPECIFIED ELEVATED LIVER ENZYMES DURING THEIR SAFETY CALL WITH HER. SHE WILL CALL ME AND LET ME KNOW WHEN SHE IS DISCHARGED AND I WILL REQUEST RECORDS THEN.'	douglas winter (b) (4)	15 Dec 2020 12:57:57

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Dec 2020 12:57:57

US3222032

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
User entered '0'	System	15 Dec 2020 12:57:57

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:04:31

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 15:31:42
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:29:38

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
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.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:32:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:32:14
Data point term sent to Coder	System	06 Oct 2020 17:31:09
User entered 'AMLODIPINE'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:30:21

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'HYPERTENSION'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:30:21

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '5'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'twice daily (BID)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 1980'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:21
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	06 Oct 2020 17:30:21

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:30:21

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:30:21

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 17:32:14
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:32:14
Data point term sent to Coder	System	06 Oct 2020 17:31:09
User entered 'ATORVASTATIN'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'HYPERCHOLESTEROLEMIA'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '40'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'once daily (QD)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 1980'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:30:49
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:30:49

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Oct 2020 17:33:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:33:19
Data point term sent to Coder	System	06 Oct 2020 17:32:11
User entered 'CARVEDILOL'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:31:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'HYPERTENSION'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '25'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'once daily (QD)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:31:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 1980'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:31:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:31:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:31:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:31:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 23:25:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Oct 2020 23:25:21
Data point term sent to Coder	System	06 Oct 2020 17:33:12
User entered 'FLEXERIL'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'CHRONIC BACK PAIN'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:32:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '10'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'three times daily (TID)'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 1980'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:32:18
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Oct 2020 17:32:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:32:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:32:18

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:34:16
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:34:16
Data point term sent to Coder	System	06 Oct 2020 17:33:12
User entered 'GABAPENTIN'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:33:01

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'CHRONIC BACK PAIN'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '600'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'three times daily (TID)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 2010'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:01
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	06 Oct 2020 17:33:01

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:33:01

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:33:01

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:35:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:35:21
Data point term sent to Coder	System	06 Oct 2020 17:34:13
User entered 'LEVOTHYROXINE'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:33:47

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'HYPOTHYROIDISM'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:33:47

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '200'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Other (OTHER)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'MCG'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User closed query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	(b) (4) System	06 Oct 2020 17:37:18
User entered 'other (OTHER)' reason for change: Data Entry Error	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:37:18
User opened query 'Other, specify is provided, however Frequency is not Other. Please correct.' (Site from System).	System	06 Oct 2020 17:33:47
User entered 'unknown (UNKNOWN)'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:33:47

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '6 DAYS PER WEEK'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 1981'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:33:47
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 17:33:47

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 17:33:47

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Oct 2020 17:33:47

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:36:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:36:26
Data point term sent to Coder User entered 'LOSARTAN'	System Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:15 06 Oct 2020 17:34:32

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'HYPERTENSION'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '100'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'once daily (QD)'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 1980'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:34:32
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:34:32

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:34:32

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:34:32

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:34:32

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:36:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:36:26
Data point term sent to Coder	System	06 Oct 2020 17:35:17
User entered 'MORPHINE'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:06

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'CHRONIC BACK PAIN'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:06

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '15'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'once daily (QD)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:06

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 2015'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:06
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:35:06

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:35:06

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:35:06

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:37:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:37:15
Data point term sent to Coder	System	06 Oct 2020 17:36:19
User entered 'OMEPROZOLE'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:34

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'ACID REFLUX'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:34

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '40'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'once daily (QD)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:35:34

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

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

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 2000'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Albert Garcia (b) (4)	06 Oct 2020 17:35:34
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:35:34

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:35:34

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:35:34

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:37:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:37:15
Data point term sent to Coder	System	06 Oct 2020 17:36:21
User entered 'OXYCODONE'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:09

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'CHRONIC BACK PAIN'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:09

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '5'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'once daily (QD)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 2015'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:09
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:09

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:36:09

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:36:09

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:36:09

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	06 Oct 2020 17:38:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Oct 2020 17:38:18
Data point term sent to Coder	System	06 Oct 2020 17:37:22
User entered 'VENLAFAXINE'	Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'ANXIETY'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '75'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'mg (mg)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'once daily (QD)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Oral (ORAL)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '01 Jan 2000'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered '0'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'Yes (Y)'	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered empty.	Albert Garcia (b) (4)	06 Oct 2020 17:36:41
	(b) (4)	

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
User entered 'No (N)'	(b) (4) Albert Garcia (b) (4) (b) (4)	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:04:31

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Oct 2020 17:36:41

US3222032

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:04:31

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 18:14:22
	(b) (4)	
User entered 'No (N)'	Amber Vasquez (b) (4)	09 Oct 2020 15:03:51
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'USA-US104-2020-MRNA-1273-P301000025'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Bruce'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Teresa'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Rankin'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Becker'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '860 Peachwood Ave'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Deland'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Houston'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 14:38:13
User entered empty.	System	23 Apr 2021 14:38:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'FL'	douglas winter (b) (4)	20 Apr 2021 19:45:50
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '32720'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '77081'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'US'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:38:13
User entered '4'	System	13 Apr 2021 15:52:31
User entered '3'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
	(b) (4)	
User entered '2'	System	22 Dec 2020 20:20:54
User entered '1'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'USA-US104-2020-MRNA-1273-P301000025'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Bruce'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Teresa'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Rankin'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Becker'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '860 Peachwood Ave'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Deland'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Houston'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 14:38:13
User entered empty.	System	23 Apr 2021 14:38:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'FL'	douglas winter (b) (4)	20 Apr 2021 19:45:50
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '32720'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '77081'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'US'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:38:13
User entered '4'	System	13 Apr 2021 15:52:31
User entered '3'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
	(b) (4)	
User entered '2'	System	22 Dec 2020 20:20:54
User entered '1'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '15/Dec/2020 13:48'	(b) (4) System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:04:31

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.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'I'	(b) (4), (b) (6)	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'USA-US104-2020-MRNA-1273-P301000025'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Bruce'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Teresa'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Rankin'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Becker'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '860 Peachwood Ave'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '6550 Mapleridge Street'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Deland'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Houston'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 14:38:13
User entered empty.	System	23 Apr 2021 14:38:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'FL'	douglas winter (b) (4)	20 Apr 2021 19:45:50
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '32720'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '77081'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'US'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:38:13
User entered '4'	System	13 Apr 2021 15:52:31
User entered '3'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
	(b) (4)	
User entered '2'	System	22 Dec 2020 20:20:54
User entered '1'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered '22/Dec/2020 12:20'	(b) (4) System	22 Dec 2020 20:20:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:04:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	02 Apr 2021 12:20:35
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 20:20:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'USA-US104-2020-MRNA-1273-P301000025'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Bruce'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Teresa'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Rankin'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Becker'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '860 Peachwood Ave'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Deland'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Houston'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 14:38:13
User entered empty.	System	23 Apr 2021 14:38:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'FL'	douglas winter (b) (4)	20 Apr 2021 19:45:50
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '32720'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '77081'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'US'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:38:13
User entered '4'	System	13 Apr 2021 15:52:31
User entered '3'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
	(b) (4)	
User entered '2'	System	22 Dec 2020 20:20:54
User entered '1'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:31

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered '02/Apr/2021 08:20'	(b) (4) System	02 Apr 2021 12:20:49

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:04:31

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)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 12:20:49

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'USA-US104-2020-MRNA-1273-P301000025'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Bruce'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Teresa'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Rankin'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Becker'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '860 Peachwood Ave'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	
	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Deland'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Houston'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 14:38:13
User entered empty.	System	23 Apr 2021 14:38:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'FL'	douglas winter (b) (4)	20 Apr 2021 19:45:50
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '32720'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '77081'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'US'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:38:13
User entered '4'	System	13 Apr 2021 15:52:31
User entered '3'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
	(b) (4)	
User entered '2'	System	22 Dec 2020 20:20:54
User entered '1'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
User entered '13/Apr/2021 11:52'	(b) (4) System	13 Apr 2021 15:52:31

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:04:31

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.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 15:52:31

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'USA-US104-2020-MRNA-1273-P301000025'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Serious

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Death

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Yes (Y)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'No (N)'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Bruce'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Teresa'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Rankin'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered 'Becker'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '860 Peachwood Ave'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	15 Dec 2020 18:48:44
User entered '6550 Mapleridge Street'	(b) (4), (b) (6)	15 Dec 2020 18:46:36
	System	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered 'Deland'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered 'Houston'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
	(b) (4)	
Un-reviewed for Safety.	System	23 Apr 2021 14:38:13
User entered empty.	System	23 Apr 2021 14:38:13
Reviewed for Safety.	(b) (4), (b) (6)	23 Apr 2021 14:37:55
User entered 'FL'	douglas winter (b) (4)	20 Apr 2021 19:45:50
	(b) (4)	

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 15:52:16
User signature succeeded.	Bruce Rankin (b) (4)	07 Apr 2021 17:29:05
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 12:20:49
Signature has been broken.	System	02 Apr 2021 12:20:49
User entered '32720'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 18:48:44
User entered '77081'	System	15 Dec 2020 18:46:36

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 21:06:07
User entered 'US'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form

Generated On: 09 Jun 2021 16:04:31

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	23 Apr 2021 14:38:13
User entered '4'	System	13 Apr 2021 15:52:31
User entered '3'	System	02 Apr 2021 12:20:49
User signature succeeded.	Bruce Rankin (b) (4)	16 Feb 2021 19:19:07
	(b) (4)	
User entered '2'	System	22 Dec 2020 20:20:54
User entered '1'	System	15 Dec 2020 18:48:54

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:31

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
User entered '23/Apr/2021 10:38'	(b) (4) System	23 Apr 2021 14:38:13

US3222032

Folder: SAE USA-US104-2020-MRNA-1273-P301000025

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:04:31

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.	Bruce Rankin (b) (4)	26 Apr 2021 13:34:36
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:38:13